

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effects of virtual reality-based trainings and conventional trainings on anticipatory and compensatory strategies while ball kicking in soccer-players with chronic ankle instability

Protocol summary

Study aim

comparison of the effect of virtual reality-based training and conventional trainings on anticipatory and compensatory strategies while ball kicking in football-players with chronic ankle instability.

Design

parallel group trial,blinded with design of 56 patients.randomization was done with randomization.com

Settings and conduct

after assessments,each patient will be treated in control or intervention group for 12 sessions.48 hours after last session they will be re-assessed.Assessment will be held in laboratory of rehabilitation faculty. Third person out of the research will code data in a way that they are unclear.Then they will be handed to analyzer and he/she will analyze data with software, then the former third person will put data in SPSS.

Participants/Inclusion and exclusion criteria

soccer players age between 18-35 with unilateral chronic ankle instability and recurrent ankle sprain with moderate to vigorous physical activity with no history of fracture of surgery in lower limb.

Intervention groups

Intervention group:Balance training and strengthening with Wii fit games:table tilt ,penguin fishing ,soccer heading,tightrope walk,single leg extension and torso twist Control group:Stretching and ankle musculature strengthening exercises with progressive Neuro-Muscular exercises.

Main outcome variables

reducing feeling of ankle instability,improvement in functional tests,improvement in muscle function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230124057197N1**

Registration date: **2023-06-30, 1402/04/09**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-30, 1402/04/09**

Update count: **0**

Registration date

2023-06-30, 1402/04/09

Registrant information

Name

Rezvane Faghihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4407 6493

Email address

rezvane.fa76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-25, 1401/12/06

Expected recruitment end date

2023-09-28, 1402/07/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of virtual reality-based

trainings and conventional trainings on anticipatory and compensatory strategies while ball kicking in soccer-players with chronic ankle instability

Public title

Virtual Reality in Chronic Ankle Instability

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Soccer player with moderate to vigorous physical activity
History of first Unilateral Ankle Sprain incident At least 12Month Before Enrollment(The Last Sprain Should be At least For 3month ago) Feeling of instability or Recurrent Giving Way in the Past Year Cumberland Ankle instability Tool Score ≤ 24 No History of Neurological or Psychological Impairments No History of Surgery or Fracture in Ankle or lower limb

Exclusion criteria:

participants who refuse to participate in trial for any reason
participants who Refuse to Continue Participating
Due to Pain or any other Reason Acute inflammation/Pain

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

the participants are randomly assigned to either the intervention group or the control group with a 1:1 allocation ratio.randomization is performed using a web-based randomization service (WWW.randomization.com). Random allocation is carried out by a third party not involved in the study.details of the allocated groups are written on cards and placed inside sequentially numbered,opaque,sealed envelopes.in this way ,the allocation sequence was concealed from the main researches

Blinding (investigator's opinion)

Single blinded

Blinding description

Third person out of the research will code data in a way that they are unclear.Then they will be handed to analyzer and he/she will analyze data with software, then the former third person will put data in SPSS.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethiques Committees of School of Nursing and Midwifery & Rehabilitation-Tehran University o

Street address

6th floor, Central Building Tehran University of Medical Science, Qods Street Cross Section, Keshavarz Blv

City

Tehran

Province

Tehran

Postal code

9128398903

Approval date

2023-01-21, 1401/11/01

Ethics committee reference number

IR.TUMS.FNM.REC.1401.149

Health conditions studied

1

Description of health condition studied

Chronic Ankle Instability

ICD-10 code

M25.373

ICD-10 code description

Other instability, unspecified ankle

Primary outcomes

1

Description

Normalized Integrated Electromyography of Proneus Longous ,soleous,Rectus Femoris,Biceps Femoris,Gluteous Medious of the Injured Leg

Timepoint

Before First Session of Intervention and 24-72 Hours
After the Last Session

Method of measurement

DataLOG for Portable Data Acquisition and Monitoring

Secondary outcomes

1

Description

Covered Distance in Y-Balnce Test in Anterior/Posterior-Medial and Posterior-Lateral Directions

Timepoint

Before The First Session of Intervention and 24-72 Hours
After the Last Session

Method of measurement

Strip Meter

2

Description

feeling of ankle instability

Timepoint

Before The First Session of Intervention and 24-72 Hours
After the Last Session

Method of measurement

Cumberland Ankle Instability Tool

Intervention groups

1

Description

Intervention group: Patients will be treated by Nintendo Wii fit for 12 Sessions (3 sessions, 4 weeks) for 1 hour. All in all they will play 6 games which Single leg extension and Torso twist are categorized in Strengthening Games and table tilt, Soccer heading, Tightrope walk, Penguin fishing are categorized in balance group. Patients move the avatar and gain points with shifting their weight on Wii board.

Category

Treatment - Other

2

Description

Control group: patients will do theraband strengthening exercises, stretching and jumping. They have to perform task while maintaining their balance on different surfaces.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Physical Education and Sport Sciences

Full name of responsible person

Mohammad Karimizade

Street address

between 15th and 16th St., North Kargar st.

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5664646464

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotohi

Street address

6th floor., Faculty of Research and Information
Technology., Qods St., Keshavarz Blv

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Rezvane Faghihi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available