

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the Effects of Virtual reality and conventional training on functional ability and neurocognitive function in athletes with Functional Ankle Instability

Protocol summary

Study aim

Comparison of the effects of Virtual reality and conventional training on functional ability and neurocognitive function in athletes with Functional Ankle Instability

Design

This is a Matched Randomized Clinical Trial Study

Settings and conduct

The intervention consists of a 4-week training program. The control group performs the conventional exercises and subjects in the experimental group perform Wii Fit Plus games. Functional performance tests include the Star Excursion Balance Test (SEBT), 8-hop, side hop, and single hop tests. The neurocognitive function assesses with the Deary-Liewald reaction task (DLRT) including simple and choice reaction times and error rate. To assess subjective-sense of instability, we use CAIT. All assessments have performed before, Immediately after the end of the intervention, and a month after the end of the intervention. All training and assessments run in the Karaj Revolutionary Sports Complex.

Participants/Inclusion and exclusion criteria

Cumberland Ankle Instability Tool score lower than 24, not participating in other rehabilitation exercise programs

Intervention groups

Twelve training sessions (three days per week) are conducted in both groups. In the experimental group, athletes have performed Wii Fit Plus games and in the control group, athletes have performed the conventional training.

Main outcome variables

Neurocognitive reaction time Number of errors in the neurocognitive test Reach distance in SEBT Jump distance in single hop test The elapsed time in the 8-hop and side hop tests CAIT score

General information

Reason for update

complete the study

Acronym

IRCT registration information

IRCT registration number: **IRCT20090301001722N19**

Registration date: **2018-05-07, 1397/02/17**

Registration timing: **prospective**

Last update: **2020-05-11, 1399/02/22**

Update count: **1**

Registration date

2018-05-07, 1397/02/17

Registrant information

Name

Samira Karimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 3939

Email address

hadianrs@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2018-05-10, 1397/02/20

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2018-05-22, 1397/03/01

Actual recruitment end date

2019-06-22, 1398/04/01

Trial completion date

2019-07-24, 1398/05/02

Scientific title

Comparison of the Effects of Virtual reality and conventional training on functional ability and neurocognitive function in athletes with Functional Ankle Instability

Public title

Comparison of the Effect of Virtual Reality training and conventional training in athletes with Functional Ankle Instability

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male athletes are 19-25 years old They have at least one significant unilateral inversion sprain of either ankle followed by more than one repeated injury or the perception of the ankle "giving-way," within the last year No evidence of mechanical instability; that assessed by the anterior drawer and talar tilt tests No history of ankle injury within the 3 months before participation No ankle surgery, no vestibular or respiratory disorder, no cognitive deficit (A score of 23 or less in Mini-Mental State Examination), no diabetes or recent lower-limb or low back pathology A Cumberland Ankle Instability Tool score lower than 24 Not participating in other rehabilitation exercise programs

Exclusion criteria:

Report any pain Reluctant to continue the tests Use any medication with possible effects on neurocognitive function or functional ability

Age

From **18 years** old to **25 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **40**

Actual sample size reached: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

In the matched pairs design athletes were pair-matched in terms of age, height, weight, duration of physical activity, and lower-limb dominance and then randomly assigned (block randomization) in two equal experimental and control groups using the Random Allocation Software.

Blinding (investigator's opinion)

Single blinded

Blinding description

All tests are conducting by a physiotherapist who is blind to the assignment and type of training of athletes that perform by the second physiotherapist

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of School of Rehabilitation, Tehran University of Medical Science

Street address

School of Rehabilitation, Piche Shemiran, Enghelab Ave, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

65111-11489

Approval date

2017-08-19, 1396/05/28

Ethics committee reference number

IR. TUMS. FNM. REC. 1396. 3235

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**

Neurocognitive reaction time

Timepoint

Before the intervention, Immediately after the end of the intervention, A month after the end of the intervention

Method of measurement

Measurement tool: DLRT software, Measurement scale: milliseconds

2**Description**

Number of errors in neurocognitive test

Timepoint

Before the intervention, Immediately after the end of the intervention, A month after the end of the intervention

Method of measurement

Measurement tool: DLRT software, Measurement scale: Number

3

Description

Reach distance in SEBT

Timepoint

Before the intervention, Immediately after the end of the intervention, A month after the end of the intervention

Method of measurement

Measurement tool: Meter, Measurement scale: Meter

4

Description

Jump distance in single hop test

Timepoint

Before the intervention, Immediately after the end of the intervention, A month after the end of the intervention

Method of measurement

Measurement tool: Meter, Measurement scale: Meter

5

Description

The elapsed time to perform the 8-hop and side hop tests

Timepoint

Before the intervention, Immediately after the end of the intervention, A month after the end of the intervention

Method of measurement

Measurement tool: Stopwatch, Measurement scale: milliseconds

6

Description

Subjective-sense of instability

Timepoint

Before the intervention, Immediately after the end of the intervention, A month after the end of the intervention

Method of measurement

Cumberland Ankle Instability Tool score (CAIT)

Secondary outcomes

empty

Intervention groups

1

Description

In the experimental group, athletes have performed Wii Fit Plus games including balance training games (e.g. Soccer heading, Ski slalom, Tight rope walk, Table tilt), and strengthening exercises (e.g. Single leg extension, Sideways leg lift, Single leg twist, Rowing squat). In balance training games the athlete stands on the Wii balance board and maintains his balance by shifting his weight during the games. In strengthening games, the

athlete stands on the board, and in each game during the specific movements, he must limit the gravity point movements to earn more points.

Category

Rehabilitation

2

Description

In the control group, athletes have performed conventional exercises including plantar flexion, dorsiflexion, inversion, and eversion movements with Thera-Band and exercising with the balance board. Training with Thera-Band is performed in three sets with ten repetitions for each movement and is performed in the first, second, third, and fourth weeks, with red, green, blue, and black, respectively. To determine Thera-Band resistance during the ankle movements, 70% of leg length is considered as Thera-Band length, for each athlete. The athletes stand on the balance board and move the front edge against the floor then move the board back, in the first week. During exercise, the board should not touch the floor. In the second week, they move the left and right edges against the floor, and in the last two weeks, circular movements are performed. (they continue the movement for 15 seconds; rest for 10 seconds; repeat this trend 10 times).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Enqelab Sports Complex

Full name of responsible person

Dr.Mohammad-Reza Hadian Rasanani

Street address

Neshat Sports Hall, Sports Complex, Enqelab Sports Complex, Karaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Keshavarz Buluv. Ghods Cross

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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**

School of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Niloofar Mohammadi

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Tehran University of Medical Sciences

Full name of responsible person

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Position

Ph.D. candidate

Latest degree

Master

Other areas of specialty/work

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Web page address**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