Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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
Ḍr.Mohammad-Reza Hadian Rasanani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Amirali Sohrabpor

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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
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Person responsible for updating data

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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