Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effects of Sensory Targeted Ankle Rehabilitation Strategies on Static and Dynamic Balance in Athletes with Chronic Ankle Instability

Protocol summary

Study aim
The Effects of Sensory Targeted Ankle Rehabilitation Strategies on Static and Dynamic Balance in Athletes with Chronic Ankle Instability

Design
Clinical trial with a control group, with parallel groups, one-way blind, randomized, on 51 patients (3 groups of 17 people).

Settings and conduct
This study will be conducted as a clinical trial at the Neuromuscular Rehabilitation Research Center in Semnan. The assessment will be carried out by two evaluators without knowing the nature of the evaluation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 45-18 years; At least 90 minutes of aerobic exercise or equivalent activity per week; Score higher than 4 in the Ankle Instability Instrument (AII). Exclusion criteria: Acute ankle sprain within the last 6 weeks; Specific balance and vision problems; Acute lower limb problems and a history of lower limb surgery to correct or repair internal disorders; Head injury (in last 6 weeks).

Intervention groups
Intervention group 1: In this group, patients will perform progress-based balance exercises for 4 weeks (3 sessions of 20 minutes per week) according to the protocol. Intervention group 2: In this group, patients will perform progress-based balance exercises for 4 weeks (3 sessions of 20 minutes per week) according to the protocol. Before each balance training session, they will receive a 5-minute set of sensory targeted ankle rehabilitation strategies treatments (leg muscle stretching, sole massage, ankle joint mobilization, and ankle joint stretching). Control group: There is no intervention and it is only for comparison with the intervention group.

Main outcome variables
Static balance tests; Dynamic balance tests.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151228025732N71**
Registration date: **2022-04-17, 1401/01/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-17, 1401/01/28**
Update count: **0**

Registration date
2022-04-17, 1401/01/28

Registrant information

Name
Alireza Emadi

Name of organization / entity
Semnan University of Medical Sciences, Semnan, Iran

Country
Iran (Islamic Republic of)

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+98 23 3345 1336

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are20935@semums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date
2022-10-12, 1401/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effects of Sensory Targeted Ankle Rehabilitation Strategies on Static and Dynamic Balance in Athletes with Chronic Ankle Instability

Public title
The Effects of Sensory Targeted Ankle Rehabilitation Strategies on Static and Dynamic Balance in Athletes with Chronic Ankle Instability

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 45-18 years At least 90 minutes of aerobic exercise or equivalent activity per week Score higher than 4 in the Ankle Instability Instrument (AII)
Exclusion criteria:
Acute ankle sprain within the last 6 weeks Specific balance and vision problems Acute lower limb problems and a history of lower limb surgery to correct or repair internal disorders Head injury (in last 6 weeks)

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **51**

Randomization (investigator's opinion)
Randomized

Randomization description
We will construct 6 blocks in ABC, ACB, BAC, BCA, CAB, and CBA using three blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 17 units of 3 blocks will be selected so that we consider having 17 people in the group (A), 17 people in the group (B) and 17 people in the group (C). Therefore, we will do block randomization.

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessment will be carried out by two evaluators without knowing the nature of the evaluation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan

City
Semnan

Province
Semnan

Postal code
3514799442

Approval date
2022-01-24, 1400/11/04

Ethics committee reference number
IR.SEMUMS.REC.1400.290

Health conditions studied

1

Description of health condition studied
Chronic Ankle Instability

ICD-10 code
M12.07

ICD-10 code description
Chronic postrheumatic arthropathy [Jaccoud], ankle and foot

Primary outcomes

1

Description
Static balance tests

Timepoint
Before the intervention, 24 hours after the intervention and 1 month after the intervention.

Method of measurement
Biodex device

2

Description
Dynamic balance tests

Timepoint
Before the intervention, 24 hours after the intervention and 1 month after the intervention.

Method of measurement
Biodex device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, patients will perform progress-based balance exercises for 4 weeks (3

sessions of 20 minutes per week) according to the protocol.

Category

Treatment - Devices

2

Description

Intervention group 2: In this group, patients will perform progress-based balance exercises for 4 weeks (3 sessions of 20 minutes per week) according to the protocol. Before each balance training session, they will receive a 5-minute set of sensory targeted ankle rehabilitation strategies treatments (leg muscle stretching, sole massage, ankle joint mobilization, and ankle joint stretching).

Category

Treatment - Devices

3

Description

Control group: There is no intervention and it is only for comparison with the intervention group.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Ziaeddin Safavi-Farokhi

Street address

Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Ziaeddin Safavi-Farokhi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available