

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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 (All).  
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)

##### Phone

+98 23 3345 1336

##### Email address

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 (All)

### 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.

#### City

Semnan

#### Province

Semnan

#### Postal code

3513138111

#### Phone

+98 23 3365 4180

#### Email

are20935@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Semnan University of Medical Sciences

#### Full name of responsible person

Majid Mirmohammadkhani

#### Street address

Semnan University of Medical Sciences, Basij Blvd

#### City

Semnan

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Semnan

#### Postal code

3514799442

#### Phone

+98 23 3345 1336

#### Email

majidmirmohammadkhani@yahoo.com

### 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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Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Semnan University of Medical Sciences

#### Full name of responsible person

Ziaeddin Safavi-Farokhi

**Position**

Associate professor

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Fatemeh Shirmohamadi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Province**

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**Postal code**

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**Email**

are20935@gmail.com

**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