

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of eight weeks of corrective intervention on lower extremity muscle electrical activity in women with limited ankle dorsiflexion

#### Protocol summary

##### Study aim

To determine the effect of eight weeks of corrective intervention on lower extremity muscle electrical activity in women with limited ankle dorsiflexion

##### Design

A clinical trial with a control group, parallel groups, single-blinded, randomized

##### Settings and conduct

Athletes with limited ankle dorsiflexion will be included in the study if they are eligible and will be randomly assigned to the intervention and control groups based on allocation concealment using the SNOSE method. This study will be conducted in a single-blind way so that the outcome assessors will not know about the allocation of the study groups and the reason for their presence in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: talocrural dorsiflexion range of motion less than 17 degrees with the knee extension, having at least three years of regular sports experience, and having a normal BMI (20-25). Exclusion criteria: functional and mechanical instability of the ankle joint, history of ankle sprain in the last year, history of fracture or surgery in the lower extremity and having postural abnormalities, and history of ligament or meniscus injury in the knee.

##### Intervention groups

The intervention group will receive rehabilitation exercises that include fascia release and triceps surae muscle, stretching and strength of shin muscle, and talocrural joint mobilization for 8 weeks and 3 sessions of 1 hour each week. To perform exercises, equipment such as straps, and tools that help the mobility of soft tissue will be used. Control group: no intervention.

##### Main outcome variables

Electromyographic activity of ankle muscle

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190224042827N4**

Registration date: **2022-11-05, 1401/08/14**

Registration timing: **retrospective**

Last update: **2022-11-05, 1401/08/14**

Update count: **0**

##### Registration date

2022-11-05, 1401/08/14

##### Registrant information

##### Name

Farzane Ramezani

##### Name of organization / entity

Bu Ali Sina University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 1423

##### Email address

f.ramezani@phe.basu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-12, 1401/07/20

##### Expected recruitment end date

2022-10-22, 1401/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of eight weeks of corrective intervention on lower extremity muscle electrical activity in women with limited ankle dorsiflexion

## Public title

Effect of rehabilitation program exercises on limited ankle dorsiflexion

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having ankle dorsiflexion range of motion less than 17 degrees Having at least three years of regular sports experience Having a normal BMI (20-25)

### Exclusion criteria:

Functional and mechanical instability of the ankle joint History of ankle sprain in the last year History of fracture or surgery in the lower extremity and having postural abnormalities History of ligament or meniscus injury in the knee

## Age

From **15 years** old to **25 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization is based on the Random Number Generator software and uses the SNOSE method to assign double groups based on the allocation concealment. The randomization of subjects was done in two stages. First, each of the subjects chooses a number between 1-30 using a lottery, then fifteen random numbers are selected between the numbers 1-30 using the Random number generator software, and according to the generated numbers, the chosen numbers of subjects are divided into two groups.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, the outcome assessors (laboratory technicians) are asked to take the desired tests from the clients. They will be unaware of the purpose of the research, the allocation of study groups, and the reason for the clients' presence in the laboratory, and they will only evaluate the variables and record their observations.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Bu Ali Sina University

##### Street address

Bu Ali Sina University, Abu Taleb St, Modares Quarter, Hamedan

##### City

Hamedan

##### Province

Hamadan

##### Postal code

3869565178

#### Approval date

2021-10-13, 1400/07/21

#### Ethics committee reference number

IR.BASU.REC.1400.042

## Health conditions studied

### 1

#### Description of health condition studied

Ankle injury

#### ICD-10 code

S99.9

#### ICD-10 code description

Unspecified injury of ankle and foot

## Primary outcomes

### 1

#### Description

Electromyographic activity of ankle muscle

#### Timepoint

Before the intervention begins, One day after the end of the intervention

#### Method of measurement

Electromyographic device

## Secondary outcomes

### 1

#### Description

Impairment of muscle activity

#### Timepoint

Before and after intervention

#### Method of measurement

Surface Electromyography Device Model Data Log p3 X8

## Intervention groups

### 1

#### Description

Intervention group: rehabilitation program exercise, exercises will be 3 sessions of 1 hour per week for 8 weeks, and equipment will be used for exercises such as a strap, instrument assisted soft tissue mobilization. The rehabilitation exercise protocol of the study includes a release of facia and triceps surae muscle, stretching and strength of shin muscle, and talocrural joint mobilization.

#### Category

Rehabilitation

### 2

#### Description

Control group: No intervention.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Committee of sport of Bu-Ali Sina University

##### Full name of responsible person

Tahereh Sohrabi

##### Street address

Bu Ali Sina University, Abu Taleb St, Modares Quarter, Hamedan

##### City

Hamedan

##### Province

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##### Postal code

3869565178

##### Phone

+98 81 3838 1423

##### Email

haniesohrabi1614@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bu Ali Sina University

##### Full name of responsible person

Dr Arash Ghorbani Choghamarani

##### Street address

Bu Ali Sina University, Abu Taleb St, Modares Quarter, Hamedan

##### City

Hamedan

##### Province

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##### Postal code

3869565178

##### Phone

+98 81 382702070

##### Email

a.ghorbani@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Bu Ali Sina University

#### 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

Bu Ali Sina University

##### Full name of responsible person

Tahereh Sohrabi

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Sport Rehabilitation

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## Person responsible for scientific inquiries

#### Contact

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**Person responsible for updating data****Contact****Name of organization / entity**

Bu Ali Sina University

**Full name of responsible person**

Farzane Ramezani

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**Latest degree**

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**Other areas of specialty/work**

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**Fax****Email**

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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