

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

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

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

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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