# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)

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+98 81 3838 1423

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**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
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Bu Ali Sina University
**Full name of responsible person**
Dr Arash Ghorbani Choghamarani
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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**
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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