

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### The effect of eight weeks of gluteal muscle strengthening exercises on Sensorimotor Function, balance and ankle instability in women with chronic ankle instability

#### Protocol summary

##### Study aim

The effect of eight weeks of gluteal muscle strengthening exercises on Sensorimotor Function, balance and ankle instability in women with chronic ankle instability

##### Design

A clinical trial with a control group with parallel groups, without blinding, randomized with the rand function of Excel software, on 30 subjects.

##### Settings and conduct

After filling the CAIT questionnaire by the students of Shahrekord University and obtaining a score of less than 24, the students will be taken to the physiology laboratory and the weakness of the middle and large gluteal muscles will be examined. Then, eligible and volunteer participants in this study will be randomly divided into two intervention and control groups. The intervention group will do their exercises for eight weeks, three sessions a week at Shahrekord University Club. After eight weeks, the evaluations will be repeated again.

##### Participants/Inclusion and exclusion criteria

History of ankle sprain in the last 2 years Having at least two ankle sprains in the last 6 months Getting a score from the post-test (score zero to 24 of the Cumberland CAIT questionnaire) non-athlete Voluntary consent of the subjects Weakness of the middle palate Great satire weakness Female students aged 18 to 40 No history of surgery No history of fracture No history of neurological diseases Not using drugs that affect the nervous system, such as sedatives, on the day of the test No balanced hearing problems No pain in any part of the body

##### Intervention groups

An intervention group A control group

##### Main outcome variables

Sensorimotor function, balance, ankle instability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231022059811N1**

Registration date: **2023-11-06, 1402/08/15**

Registration timing: **prospective**

Last update: **2023-11-06, 1402/08/15**

Update count: **0**

##### Registration date

2023-11-06, 1402/08/15

##### Registrant information

##### Name

maedeh kafami ladani

##### Name of organization / entity

The university of shahrekord

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3772 0619

##### Email address

maedehkafami77@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-11, 1402/08/20

##### Expected recruitment end date

2024-01-15, 1402/10/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                  |
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| empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Blinding (investigator's opinion)</b><br>Not blinded                                                                                                                                                                                                                                                                                          |
| <b>Scientific title</b><br>The effect of eight weeks of gluteal muscle strengthening exercises on Sensorimotor Function, balance and ankle instability in women with chronic ankle instability                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Blinding description</b><br><b>Placebo</b><br>Not used                                                                                                                                                                                                                                                                                        |
| <b>Public title</b><br>The effect of gluteal muscle strengthening exercises on ankle instability                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Assignment</b><br>Parallel                                                                                                                                                                                                                                                                                                                    |
| <b>Purpose</b><br>Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Other design features</b>                                                                                                                                                                                                                                                                                                                     |
| <b>Inclusion/Exclusion criteria</b><br><b>Inclusion criteria:</b><br>History of ankle sprain in the last 2 years Having at least two ankle sprains in the last 6 months Obtaining a score from the questionnaire (score zero to 24 of the Cumberland CAIT questionnaire) non-athlete Voluntary consent of the subjects Weakness of the gluteus medius Weakness of the gluteus maximus Female students aged 18 to 40 No history of surgery No history of fracture No history of neurological diseases Not using drugs that affect the nervous system, such as sedatives, on the day of the test No balanced hearing problems No pain in any part of the body<br><b>Exclusion criteria:</b><br>No history of ankle sprain in the last 2 years Not having at least two ankle sprains in the last 6 months Failure to obtain a grade from the transcript (CAIT more than 24) athlete Lack of voluntary consent of subjects Absence of weakness of gluteus medius Absence of weakness of gluteus maximus Female or male students less than 18 or more than 40 History of surgery History of fracture History of neurological diseases Using drugs that affect the nervous system, such as sedatives, on the day of the test Pain in any part of the body | <b>Secondary Ids</b><br>empty                                                                                                                                                                                                                                                                                                                    |
| <b>Age</b><br>From <b>18 years</b> old to <b>40 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Ethics committees</b><br><b>1</b><br><b>Ethics committee</b><br><b>Name of ethics committee</b><br>Ethics Committee of Shahrekord University<br><b>Street address</b><br>University Shahrekord, Rahbar Blvd<br><b>City</b><br>Sharekord<br><b>Province</b><br>Chahar-Mahal-va-Bakhtiari<br><b>Postal code</b><br>8818634141                   |
| <b>Gender</b><br>Female                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Approval date</b><br>2023-06-12, 1402/03/22<br><b>Ethics committee reference number</b><br>IR.SKU.REC.1402.014                                                                                                                                                                                                                                |
| <b>Phase</b><br>N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Health conditions studied</b><br><b>1</b><br><b>Description of health condition studied</b><br>ankle sprain<br><b>ICD-10 code</b><br><b>ICD-10 code description</b>                                                                                                                                                                           |
| <b>Groups that have been masked</b><br><i>No information</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Primary outcomes</b><br><b>1</b><br><b>Description</b><br>Cumberland questionnaire and gluteal muscle weakness<br><b>Timepoint</b><br>Pre-test and post-test<br><b>Method of measurement</b><br>The method of measuring gluteal weakness is done by hand dynamometer, and subjects should score less than 24 in the Cumberland Questionnaire. |
| <b>Sample size</b><br>Target sample size: <b>30</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Secondary outcomes</b><br><b>1</b><br><b>Description</b><br>Sensorimotor function, balance, ankle instability                                                                                                                                                                                                                                 |
| <b>Randomization (investigator's opinion)</b><br>Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                  |
| <b>Randomization description</b><br>Randomization method: simple randomization<br>Randomization Unit: Individual Randomization tools: Lottery using cards and bowls How to create a random sequence and concealment: First, the names of 30 students with ankle instability and weakness of the middle and large pelvis were written on a sheet as a statistical population, and the sheets were folded and thrown into a bowl. Then I separate two bowls and put one of the papers in one bowl and the other paper in the other bowl and continue doing this until the last paper and in the end there are 15 papers in each bowl, one of the bowls is the intervention group and the other is the intervention group. We will choose control.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                  |

**Timepoint**

Pre-test and post-test

**Method of measurement**

How to measure sensorimotor function with a goniometer, balance is measured by static and dynamic tests with a stopwatch, and ankle instability is measured with the identification of function ankle instability questionnaire.

**Intervention groups****1****Description**

Intervention group: They will do gluteal strengthening exercises for 8 weeks, 3 sessions per week and 30 minutes each session. Each exercise has 8 repetitions, each movement is performed with a 2 second pause and 2 minutes of rest between each exercise. After 4 weeks, by adding weight to each of the exercises, the level of muscle activation can be increased, which causes more strengthening effects.

**Category**

Rehabilitation

**2****Description**

Control group: There was no intervention and they went about their daily lives.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahrekord University

**Full name of responsible person**

maedeh kafami ladani

**Street address**

Shahrekord University, Rahbar Blvd

**City**

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**Email**

maedehkafami77@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahrekord University

**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**

Shahrekord University

**Proportion provided by this source**

50

**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**

The University of Shahrekord

**Full name of responsible person**

Maedeh kafami ladani

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Sports science

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Shahrekord University

**Full name of responsible person**

Maedeh kafami ladani

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Sports science

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## **Person responsible for updating data**

### **Contact**

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**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

People's information will remain confidential and I only have the right to publish the results as a group.

**Study Protocol**

No - There is not 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