Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ranb 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

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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

empty

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

Public title
The effect of gluteal muscle strengthening exercises on ankle instability

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
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

Exclusion criteria:
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

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: simple randomization 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.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahrekord University

Street address
University Shahrekord, Rahbar Blvd

City
Sharekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8818634141

Approval date
2023-06-12, 1402/03/22

Ethics committee reference number
IR.SKU.REC.1402.014

Health conditions studied

1

Description of health condition studied
ankle sprain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Cumberland questionnaire and gluteal muscle weakness

Timepoint
Pre-test and post-test

Method of measurement
The method of measuring gluteal weakness is done by hand dynamometer, and subjects should score less than 24 in the Cumberland Questionnaire.

Secondary outcomes

1

Description
Sensorimotor function, balance, ankle instability

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 dentification 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
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Shahrekord University, Rahbar Blvd
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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
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Person responsible for scientific

inquiries

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Person responsible for updating data

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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