

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of adding gluteus medius strengthening exercise into short foot exercise in children with excessive body weight with flexible flat foot

Protocol summary

Study aim

The aim of the present study was to investigate the effect of adding gluteus medius strengthening exercises into short foot exercises in children with excessive body weight with flexible flat foot.

Design

Clinical trial with control group, single blind, randomized, parallel groups, sample size 50 people, randomization software: Random Number Generator

Settings and conduct

The tests will be conducted in the Sports Science Laboratory of the National University of Malayer by experts in the field, and then the intervention and training will take place in the Takhti Sports Hall of this city. During the testing, the outcome assessors and data analysts will be unaware of the main purpose of the research.

Participants/Inclusion and exclusion criteria

Inclusion criteria included: girls between 10 and 13 years old, has a flat, flexible foot, no history of lower limb injury or surgery, navicular bone loss index greater than 10 mm, no use of orthopedic insoles in the past six months, body mass index greater than 19 kg/m², and puberty onset. exclusion criteria included: use of orthopedic insoles, having neuromuscular problems

Intervention groups

Gluteus medius strengthening exercises and short foot exercises group, short foot exercises control group

Main outcome variables

Navicular drop greater than 10 mm

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250527065930N1**

Registration date: **2025-11-17, 1404/08/26**

Registration timing: **retrospective**

Last update: **2025-11-17, 1404/08/26**

Update count: **0**

Registration date

2025-11-17, 1404/08/26

Registrant information

Name

Mobina Roostaei

Name of organization / entity

Bu Ali Sina University

Country

Iran (Islamic Republic of)

Phone

+98 81 3830 3243

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-24, 1404/07/02

Expected recruitment end date

2025-10-04, 1404/07/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding gluteus medius strengthening exercise into short foot exercise in children with excessive body weight with flexible flat foot

Public title

The effectiveness of exercise on flat feet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Navicular bone loss index greater than 10 mm
Body mass index greater than 19 Kg/m²
Girls between 10 and 13 years old
No history of lower limb injury or surgery
Not using orthopedic insoles in the past six months
Has a flat, flexible foot
Puberty has occurred

Exclusion criteria:
Use of orthopedic insoles
Having neuromuscular problems

Age
From **10 years** old to **13 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done based on the Random Number Generator software and based on the allocation concealment using the SNOSE method. They will be assigned to two groups. We ask the software to randomly assign numbers 1 to 50 to two groups A and B. Group A is the combined group of gluteus medius and short foot strengthening exercises and group B is the short foot exercises group. We put numbers in sealed envelopes, the range of numbers is 1 to 50. The number of subjects is 50 and they will be divided into two groups of 25. Then we ask the participants to take the envelopes containing the numbers and the number that each participant chooses is divided according to the division that we have already done ourselves, which number is in which group, the person will enter the desired group and we perform this kind of randomization of the participants.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, outcome assessors, laboratory technicians, are asked to take the desired tests from the patients. These individuals will be unaware of the purpose of the study, the assignment of study groups, and the reason for their presence in the laboratory, and will only assess 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

City

Hamedan

Province

Hamadan

Postal code

6517838695

Approval date

2024-12-02, 1403/09/12

Ethics committee reference number

IR.BASU.REC.1403.037

Health conditions studied

1

Description of health condition studied

Flexible flat foot

ICD-10 code

M21.40

ICD-10 code description

Flat foot [pes planus] (acquired), unspecified foot

Primary outcomes

1

Description

Navicular drop greater than 10 mm

Timepoint

Before the intervention begins, one day after the intervention ends

Method of measurement

Stretcher

Secondary outcomes

1

Description

Balance

Timepoint

Before the intervention begins, one day after the intervention ends

Method of measurement

Dynamic balance test (Y)

2

Description

Proprioceptive

Timepoint

Before the intervention begins, one day after the intervention ends

Method of measurement

Goniometer

3

Description

Plantar pressure variables

Timepoint

Before the intervention begins, one day after the intervention ends

Method of measurement

Foot scan device

4

Description

Pain

Timepoint

Before the intervention begins, one day after the intervention ends

Method of measurement

VAS pain questionnaire

Intervention groups

1

Description

The intervention group will combine gluteus medius strengthening exercises and short-foot exercises. The exercises will be for 8 weeks and 3 sessions per week for one hour. The equipment used will include a red elastic band with a difficulty level of 4 out of 5, a tennis ball, and a step towel. The exercises will last for one hour, including 10 minutes of warm-up, 40 minutes of specialized exercises for strengthening the gluteus medius and short-foot exercises, and 10 minutes of cool-down. The target muscles in this intervention include the gluteus medius muscle, the tibialis posterior muscle, the tibialis anterior muscle, the abductor hallucis and peroneus longus muscles.

Category

Treatment - Devices

2

Description

Control group: the short foot training control group will training for 8 weeks and 3 sessions per week for one hour.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Malayer County Education Department

Full name of responsible person

Akbar Farahani

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Malayer County Education Department, Enghelab Boulevard, HamedanProvince, Malayer

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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

Mobina Roostaei

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Sports pathology and corrective exercises

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Person responsible for updating data

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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