

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of 6 Weeks Combined Training of the Intrinsic Foot Muscles and Tibialis Posterior on the Biomechanical Performance of Jumping in Women with Flexible Flat Feet

Protocol summary

Study aim

Investigation of the performance variables of the musculoskeletal system extracted from biomechanical data in functional activities in women with flat feet before and after 6 weeks of exercise therapy

Design

subjects with flat feet are randomly (with block randomization) divided into intervention (with exercise) and control (without exercise) groups. The clinical trial has a control group, double-blind, randomized with a sample size of 34. There is no trial phase.

Settings and conduct

In this study, we will have two intervention and control groups. The evaluation of jump and arch height variables for both groups will be done in two sessions with an interval of 6 weeks at the movement disorders research center of Tarbiat Modares University. The intervention group will do the exercises taught during 6 weeks, while the control group will not do any exercises. The person responsible for data collection and the person analyzing the data are not aware of the allocation of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with bilateral flexible flat feet; Normal Body Mass Index; Ages 18-45 Exclusion criteria: History of any lasting orthopedic or neurological damage in the lower limbs and spine; leg length discrepancy more than 1.5 cm; Body mass index more than 25; Obvious deformities in lower limb

Intervention groups

The intervention group will perform 6 weeks of foot exercises with elastic band and the variables will be measured before and after 6 weeks. also, the control group will not do any exercises during 6 weeks and the variables will be measured before and after that.

Main outcome variables

Biomechanical variables related to the performance of

the musculoskeletal system during functional activities such as walking, jumping and balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201128049511N5**

Registration date: **2023-10-14, 1402/07/22**

Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**

Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

Sahar Boozari

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of 6 Weeks Combined Training of the Intrinsic Foot Muscles and Tibialis Posterior on the Biomechanical Performance of Jumping in Women with Flexible Flat Feet

Public title

The Effect of Exercise Therapy on the Human Body Performance in Women with Flat Feet

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Non-athlete Women Suffering from Bilateral Flexible Flat Feet (Arch Height Ratio less than 0.221) Age 18-45 years old Normal Body Mass Index (18.5-25)

Exclusion criteria:

History of any lasting orthopedic or neurological injury in the lower limbs and spine The difference in the actual length of the lower body be more than 1.5 centimeters Significant congenital malformations in the lower limbs Body mass index more than 25 Obvious deformities such as hallux valgus, genu varus, genu valgum and internal rotation of the thigh

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this study will be done by block randomization method. Participants will be randomly assigned into intervention or control groups. The number of blocks will be 4, 6, and 8. Also, the blocks will be randomly sealed in the envelope. For random assignment, code 1 for the intervention group and code 0 for the control group are placed in the envelopes. subjects will choose an envelope and then, based on the chosen code, they are assigned in one of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The Person Recording the Lab's Data and the Person Analyzing the Data are not aware of the study group allocation.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr Bridge, Jalal Al Ahmad Highway, Tehran, Iran

City

tehran

Province

Tehran

Postal code

1411713116

Approval date

2023-05-29, 1402/03/08

Ethics committee reference number

IR.MODARES.REC.1402.035

Health conditions studied**1****Description of health condition studied**

Flexible Flat Feet

ICD-10 code

M21.4

ICD-10 code description

Flat foot [pes planus] (acquired)

Primary outcomes**1****Description**

Biomechanical variables related to jump

Timepoint

Before and after 6 weeks after intervention

Method of measurement

Force plate device

Secondary outcomes

empty

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

Intervention group: The intervention consists of 6 weeks of exercises for women with flexible flat feet. In the first session, after measuring the height of the medial arch of the foot and getting familiar with how to perform the

tests, the subject will perform the jump tests and then, the variables will be recorded. Then the person will be taught to do both short foot exercises and foot adduction exercises with an elastic band. The individuals should do these exercises for 6 weeks, with a frequency of 5 times a week and 3 sets of 10 each time. After the end of 6 weeks, the final evaluation session will be done in the laboratory like the first session.

Category

Treatment - Other

2

Description

Control group: This group will not receive any exercise and participants will be evaluated before and after 6 weeks. In the first session, after measuring the height of the medial arch of the foot and getting familiar with how to perform the tests, the subject will perform the jump tests and then, the variables will be recorded. After the end of 6 weeks, the final evaluation session will be done in the laboratory like the first session.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Research and Treatment Center for Movement Disorders of Tarbiat Modares University

Full name of responsible person

Sahar Boozari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Tarbiat Modares

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?

No

Title of funding source

University of Tarbiat Modares

Proportion provided by this source

100

Public or private sector

Private

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 Tarbiat Modares

Full name of responsible person

Sargol abolhasani

Position

Master's Student in Physiotherapy

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Latest degree

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Other areas of specialty/work

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared after people are not identified.

When the data will become available and for how long

After the results are published, the access phase started six months later

To whom data/document is available

Researchers in academic and research organizations will also have access to the data.

Under which criteria data/document could be used

To do scientific research

From where data/document is obtainable

to do scientific research, Sahar Boozari, Jalal Al Ahmad Highway, Tarbiat Modares University,
s.boozari@modares.ac.ir, 00982182885053

What processes are involved for a request to access data/document

Send the project plan, and if approved, it will be sent following a complete evaluation of the persons and organizations involved in the project.

Comments