Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of foot orthosis and short foot exercise on morphological characteristics of the intrinsic muscles of foot and plantar fascia in individuals with flexible flatfoot

Protocol summary

Study aim

Determining the effect of foot orthosis with short foot exercise on thickness and cross section area of the intrinsic muscles of the foot and plantar fascia angle in adults with flexible flat foot

Design

A clinical trial with a control group and an intervention group, with parallel groups, single-blind, randomized, on 30 patients, a simple randomization method with a sealed envelope is used.

Settings and conduct

This study is conducted on 30 adults with flexible flat feet in the laboratory of Shahid Beheshti College in Tehran. The researcher is not aware of the placement and grouping and the treatments performed. Patients are divided into two groups by simple randomization with sealed envelopes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults with flexible flat feet, the presence of heel valgus, age of 18 to 40 years, foot posture index score 6 and greater than 6, body mass index in the normal range (24.9-18.5) Exclusion criteria: Rigid flatfoot, posterior tibial tendon disfunction and acquired flatfoot due to trauma, severe degree of hallux valgus, plantar fasciitis, ankle instability, knee brace, history of trauma and orthopedic surgery in the last 6 months, pregnancy, orthopedic and inflammatory diseases, history of using foot orthosis or performing foot exercises in the 6 months before the study

Intervention groups

Control group: orthosis group alone and intervention group: orthosis and exercise group together Both groups use the orthosis at least 6 hours a day for 8 weeks. In addition to the foot orthosis, the orthosis and exercise group performs short foot exercise daily, twice a day for 8 weeks.

Main outcome variables

Plantar fascia angle, abductor hallucis thickness, abductor hallucis cross-sectional area, flexor hallucis brevis thickness, flexor hallucis brevis cross-sectional area, Foot Pasture Index score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241110063658N1**
Registration date: **2025-01-15, 1403/10/26**
Registration timing: **prospective**

Last update: **2025-01-15, 1403/10/26**
Update count: **0**

Registration date

2025-01-15, 1403/10/26

Registrant information

Name

Parand vosoughi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7763 4633

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-19, 1403/10/30

Expected recruitment end date

2025-05-21, 1404/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of foot orthosis and short foot exercise on morphological characteristics of the intrinsic muscles of foot and plantar fascia in individuals with flexible flatfoot

Public title

Insoles and exercise therapy for people with flat feet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults with flexible flatfoot The presence of heel valgus Ages 18 to 40 Foot posture index score 6 and greater than 6 Body mass index in the normal range (24.9-18.5)

Exclusion criteria:

Rigid flatfoot Posterior tibial tendon disfunction and acquired flatfoot due to trauma Severe degree of hallux valgus Plantar fasciitis Ankle instability Knee genu varum History of trauma and orthopedic surgery in the last 6 months pregnancy Orthopedic and inflammatory diseases History of using foot orthosis or performing foot exercises in the 6 months before the study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is performed using sealed envelopes, in which a box contains 30 envelopes, 15 envelopes labeled A and 15 envelopes labeled B, and patients are asked to choose one envelope. The letter A is placed in the foot orthosis alone group and the letter B is placed in the foot orthosis and leg shortening exercise group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Ultrasound evaluations are done by a person who does not know about the groupings and a statistician who is also blind to the groupings.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Tehran, Valenjak, Daneshjoo Blvd., Arabi St.,Shahid Beheshti University of Medical Sciences

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1985717443

Approval date

2024-10-16, 1403/07/25

Ethics committee reference number

IR.SBMU.RETECH.REC.1403.348

Health conditions studied

1

Description of health condition studied

Flat foot

ICD-10 code

M21.4

ICD-10 code description

Flat foot [pes planus] (acquired)

Primary outcomes

1

Description

"Plantar fascia angle with the horizontal axis"

Timepoint

The beginning of the study before the intervention and 8 weeks after using the intervention

Method of measurement

Ultrasonography

2

Description

"Abductor hallucis muscle thickness"

Timepoint

The beginning of the study before the intervention and 8 weeks after using the intervention

Method of measurement

Ultrasonography

3

Description

"Abductor hallucis muscle cross section area"

Timepoint

The beginning of the study before the intervention and 8 weeks after using the intervention

Method of measurement

Ultrasonography

4

Description

"Flexor hallucis brevis muscle thickness"

Timepoint

The beginning of the study before the intervention and 8 weeks after using the intervention

Method of measurement

Ultrasonography

5

Description

"Flexor hallucis brevis muscle cross section area"

Timepoint

The beginning of the study before the intervention and 8 weeks after using the intervention

Method of measurement

Ultrasonography

Secondary outcomes

1

Description

"foot posture index score"

Timepoint

The beginning of the study before the intervention and 8 weeks after using the intervention

Method of measurement

Observation

Intervention groups

1

Description

Control group: orthosis group alone. The CNC orthosis is scanned and made in static mode through the initial scan of the foot by the Danesh Salar scanner. The full-length orthosis has an internal longitudinal arch and metatarsal pad and is made of semi-hard EVA foam. Participants in both control and intervention groups will receive the orthosis and wear it outdoors for at least 6 hours a day for 8 weeks in walking and sports shoes. The control group does not participate in any ankle and foot exercises.

Category

Rehabilitation

2

Description

Intervention group: Intervention group: group of orthosis and exercise together. The participants in the intervention group also receive the orthosis and use it for at least 6 hours a day for 8 weeks in walking and sports shoes, and in addition to the foot orthosis, they do short foot exercise without shoes, insoles and with bare feet in a standing position. It is performed on one leg next to the wall in a position where the index finger is connected to the wall to keep the balance of the body and the knee of the other leg is in flexion. in such a way that they raise the internal longitudinal arch and shorten the length of the leg in the anterior-posterior direction and move the head of the first metatarsal to the heel; Without flexing the fingers. Exercises are repeated daily, twice a day in 3 sets of 5. In each repetition, the arch is held for 5 seconds and there is a 2 minute rest between each set. After one to two weeks of training, if the participants were able to hold the contraction without falling down the navicular tuberosity, the duration of holding will increase from 5 to 10 and the number of sets will increase from 3 to 5 sets.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Biomechanics Laboratory, Faculty of Rehabilitation, Shahid Beheshti University, Tehran

Full name of responsible person

Parand Vosoughi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Afshin Zarghi

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https://isid.research.ac.ir/Afshin_Zarghi

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Parand Vosoughi

Position
Physiotherapy Master's student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Other areas of specialty/work
Physiotherapy

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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