Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparative Study of the Effect of Insole and Ankle-foot Muscles Strengthening on Plantar Pressure in Flexible Adult Flatfoot

Protocol summary

Study aim
Comparative study of the effect of insole and ankle-foot muscles strengthening on plantar pressure in flexible adult flatfoot

Design
Semi-experimental clinical trial, with three parallel groups, without blinding, with randomization, with a sample size of 40 people.

Settings and conduct
A sample of adults aged 18 to 28 years with flexible flat feet referred to the Faculty of Rehabilitation Sciences of Iran University of Medical Sciences. 13 people for the muscle strengthening group, 13 people for the orthosis group, and 13 people for the muscle strengthening and orthosis group will be selected. The subject is evaluated for plantar pressure on the day of visit and 2 months later. The pressure of the sole of the foot is recorded with the RSscan force plate and the data is analyzed with the software.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Flexible flat foot Having pain in the foot due to the symptoms of flexible flat soles Non-entry criteria: History of injuries, fractures and dislocations in the lower limbs Malalignment of the lower limbs and spine Using one of the foot orthoses for at least 3 months before the intervention

Intervention groups
First intervention group : muscle strengthening Second intervention group: Functional foot orthosis Third intervention group: muscle strengthening and functional foot orthosis

Main outcome variables
Plantar pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221120056547N1**
Registration date: **2023-03-01, 1401/12/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-01, 1401/12/10**
Update count: **0**

Registration date
2023-03-01, 1401/12/10

Registrant information

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azadeh shahini

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-04-20, 1402/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative Study of the Effect of Insole and Ankle-foot Muscles Strengthening on Plantar Pressure in Flexible Adult Flatfoot

Public title

Effect of Insole and Exercise in Adult Flatfoot

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Flexible flat foot based on the Foot Posture Index score (6 and above) and the formation of an arch in the state of non-weight bearing Foot pain due to the symptoms of flexible flat foot Ability to follow the examiner's recommendations BMI of 19 to 25 Being 18 and older

Exclusion criteria:

Using any types of foot orthoses in at least the last 3 months before the initiation of the intervention Malalignment of the lower limb and spine including genu-valgum and genu-varum, genu-recurvatum, leg Length discrepancy, hallux valgus and other deviations of the fingers and other abnormalities. History of injury, fracture and dislocation in the lower limb and a problem that affects the musculoskeletal system (cerebral palsy, polio, rickets myopathy, thyroid disease, rheumatoid arthritis, diabetes, stroke) Ulcer or skin disorder sensory or vascular disorder

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Randomization Unit: Individual Randomization tool: Sealed envelope There is no concealment Each person participating in the study will be given 3 identical envelopes in which the name of the intended intervention will be written in each envelope. One envelope with muscle strengthening intervention, one envelope with foot orthosis intervention, one envelope with muscle strengthening intervention and foot orthosis. After choosing the envelope, the content of the envelope will be seen and the person will be considered in the group. In this study, people are aware of all types of therapeutic interventions and blinding does not occur.

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

Research Ethics Committees of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran

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Postal code

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Approval date

2022-10-19, 1401/07/27

Ethics committee reference number

IR.IUMS.REC.1401.255

Health conditions studied

1

Description of health condition studied

Flexible flat foot

ICD-10 code

Q66.5

ICD-10 code description

Congenital pes planus

Primary outcomes

1

Description

plantar pressure

Timepoint

Measurement of plantar pressure at the beginning of the study (before the start of the intervention) and 60 days after using orthosis, muscle strengthening exercises and orthosis and muscle strengthening exercises simultaneously.

Method of measurement

RSscan forceplate

Secondary outcomes

1

Description

Arch index

Timepoint

At the beginning of the study (before the start of the intervention) and after 60 days

Method of measurement

Calculation of the ratio of the area of the middle part of the foot to the whole foot by RSscan software

Intervention groups

1

Description

First intervention group: Muscle strengthening. Each person is evaluated individually. The foot posture index is determined for each person and a score is given to each person. The type of daily shoes of the person and the level of his activity are questioned. Necessary strengthening exercises, which include walking on the toe and the outer edge of the foot, gathering a towel with the toes, and pulling a rope, were given to the people of this group, and the number of times and how to repeat them were taught under the supervision of a physiotherapist to be performed at home. In addition, the examiner checks how to do the exercises on a daily and weekly basis. The plantar pressure of the foot is recorded with the RSscan device and the data is analyzed with the software. A person's walking speed is controlled by the sensors of the device.

Category

Treatment - Other

2

Description

Second intervention group: Foot orthosis. Foot posture index is determined for each person and each person is given a score. The type of daily shoes of the person and the level of his activity are questioned. A pair of functional foot orthosis is prepared for each subject. The orthoses are placed inside the appropriate shoes. It is explained to the person that he should avoid wearing inappropriate shoes while studying and it is better to use sports and medical shoes. The plantar pressure of the foot is recorded with the RSscan device and the data is analyzed with the software. A person's walking speed is controlled by the sensors of the device.

Category

Treatment - Other

3

Description

Third intervention group: Foot orthosis and Muscle strengthening. Foot posture index is determined for each person and each person is given a score. The type of daily shoes of the person and the level of his activity are questioned. A pair of functional foot orthosis is prepared for each subject. The orthoses are placed inside the appropriate shoes. It is explained to the person that he should avoid wearing inappropriate shoes while studying and it is better to use sports and medical shoes. Necessary strengthening exercises, which include walking on the toe and the outer edge of the foot, gathering a towel with the toes, and pulling a rope, were given to the people of this group, and the number of times and how to repeat them were taught under the supervision of a physiotherapist to be performed at home. In addition, the examiner checks how to do the exercises on a daily and weekly basis. The plantar pressure of the foot is recorded with the RSscan device and the data is analyzed with the software. A person's walking speed is controlled by the sensors of the device.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Orthotics and Prosthetics, Faculty of Rehabilitation, Iran University of Medical Scien

Full name of responsible person

Hassan saeedi

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Sponsors / Funding sources

1

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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

Iran 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

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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
Not applicable
Data Dictionary
Not applicable