# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**

**Name**
azadeh shahini

**Name of organization / entity**

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Iran (Islamic Republic of)

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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

**City**

Tehran

**Province**

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۱۴۴۹۶۱۴۵۳۵

**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

**Sponsor**

**Name of organization / entity**

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**Full name of responsible person**

Hossein keyvani

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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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## 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**
Not applicable
**Data Dictionary**
Not applicable