

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of adding proprioception exercises to corrective exercises on foot posture, ankle's proprioception and balance on 9- 12 years in girls with flat foot and hallux valgus

#### Protocol summary

##### Study aim

Determining the effect of adding proprioception exercises to corrective exercises on foot posture, ankle proprioception, and balance in 9-12-year-old girls with flat feet and hallux valgus

##### Design

A clinical trial study, with simple random sampling, without blinding, on 42 participants

##### Settings and conduct

Evaluations will be done before and after the intervention. Exercises in the intervention groups will be held for 6 weeks, 3 sessions for one hour each week in the correctional center of Quds city. To detect flat foot from the navicular drop test, to detect the degree of hallux valgus from the goniometer, to determine the foot posture from the foot posture index test, to measure the proprioception of the foot from the goniometer and to evaluate Static balance will be used from the bass stick test and dynamic balance will be used from the modifi star test.

##### Participants/Inclusion and exclusion criteria

The conditions of entry are:1)Girls 9 to 12 years old2:)Has flexible flat foot and hallux valgus,3)Normal body mass index The conditions of non-entry are:1)Non-participation of the subject in three consecutive session.2)causing pain during the research process.3)Orthopedic injury in the lower limb such as fracture,ankle sprain,tendon rupture,...

##### Intervention groups

Intervention group one (corrective exercises) The exercises of this group include short foot exercises, which is intervention group two (corrective exercises with proprioceptive exercises) In this group, in addition to the corrective exercises of intervention group one, proprioceptive exercises are also performed. It will be done first at a stable level and then at an unstable level. The control group will not do any type of intervention

during the 6 weeks of interventions and will only participate in the pre-test and post-test.

##### Main outcome variables

Foot posture! Ankle proprioception and balance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220723055526N1**

Registration date: **2022-08-23, 1401/06/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-08-23, 1401/06/01**

Update count: **0**

##### Registration date

2022-08-23, 1401/06/01

##### Registrant information

##### Name

Zahra Darabi

##### Name of organization / entity

Kharazmi university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3346 1763

##### Email address

zahradarabi@khu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-23, 1401/05/01

##### Expected recruitment end date

2022-09-06, 1401/06/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of adding proprioception exercises to corrective exercises on foot posture, ankle's proprioception and balance on 9- 12 years in girls with flat foot and hallux valgus

**Public title**

The effect of adding proprioception exercises to corrective exercises on foot posture, ankle's proprioception and balance in girls with flat foot and hallux valgus

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Girls 9-12 years old Has flexible flat foot and hallux valgus Normal body mass index

**Exclusion criteria:**

Lower extremity pain Over weight or obesity Non-participation of the subject in three consecutive sessions Causing pain during the research process Orthopedic injury in the lower limb such as fracture,ankle sprain,tendon rupture,...No foot surgery,systemic disease that effects the lower limb or the pasture of the foot such as cerebral palsy,rickets

**Age**

From **9 years** old to **12 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are randomly divided into three groups by hidden sealed envelope randomization method. In such a way that an equal number of types of interventions are written on sheets of the same size and the sheet is folded in such a way that the type of interventions is not clear. If the patient is selected for the study, the parents randomly take a sheet from the envelope that shows the type of interventions.

**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 Institute of Physical Education and Sports Sciences

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N3,Fifth Alley,Mir Emad Street,Ostad Motahari Street,Tehran

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**Postal code**

1587958711

**Approval date**

2022-07-20, 1401/04/29

**Ethics committee reference number**

IR.SSRC.REC.1401.043

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

Flexible flat foot

**ICD-10 code**

M21.4

**ICD-10 code description**

Flat foot [pes planus] (acquired)

**2****Description of health condition studied**

Hallux valgus

**ICD-10 code**

M20.1

**ICD-10 code description**

Hallux valgus (acquired)

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

Foot posture

**Timepoint**

Before intervention and after 6 weeks of intervention

**Method of measurement**

It is evaluated by the foot posture index

**2****Description**

Ankle proprioception

**Timepoint**

Before intervention and after 6 weeks of intervention  
**Method of measurement**  
Goniometer

### 3

#### **Description**

Balance

#### **Timepoint**

Before intervention and after 6 weeks of intervention

#### **Method of measurement**

To evaluate the static balance of the bass stick test and the dynamic balance of the modified star or Y test

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

The first intervention group: People in this group do corrective exercises for 6 weeks, 3 sessions per week and 1 hour in each session, for a total of 18 sessions. These short foot exercises will be given from the unladen position to the loaded standing positions.

#### **Category**

Rehabilitation

### 2

#### **Description**

The second intervention group: People in this group will do corrective exercises along with proprioception exercises for 6 weeks, 3 sessions per week and each session for an hour, in total 18 sessions, in such a way that these exercises will be performed on a stable surface at first and on an unstable surface in the advanced stages.

#### **Category**

Rehabilitation

### 3

#### **Description**

Control group: The control group will not do any exercises for 6 weeks and will only participate in the pre-test and post-test.

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahr Quds schools

##### **Full name of responsible person**

Zahra Darabi

##### **Street address**

No.1, 7th East Alley, Hanrestan Street, Moshiriyeh  
**City**  
Tehran  
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1855673553  
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+98 21 3346 1763  
**Email**  
darabida4@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

kharazmi University

##### **Full name of responsible person**

Malihe Hadadnezhad

##### **Street address**

Kharazmi University, Shahid Beheshti Street, Karaj

##### **City**

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##### **Province**

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##### **Postal code**

3197937551

##### **Phone**

+98 26 3457 9600

##### **Email**

m.hadadnezhad@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

No

#### **Title of funding source**

This study was conducted by researchers and no institutional funding was received

#### **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**

Persons

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

kharazmi University

##### **Full name of responsible person**

Malihe Hadadnezhad

##### **Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Corrective Exercises

**Street address**

Kharazmi University, University Square, Beheshti Street, Karaj

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Zahra Darabi

**Position**

University student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Others

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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**

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

**Title and more details about the data/document**

Only data related to demographics and outcomes are shared.

**When the data will become available and for how long**

After printing the article/Article extracted from the study

**To whom data/document is available**

The data can be displayed and shared by the Iran Clinical Trial Registration Center, journals, and academic individuals/researchers who are conducting research and scientific activities in this field upon reasonable request.

**Under which criteria data/document could be used**

Data analysis and the use of documents can only be done under the condition that their results are mentioned in systematic review articles conducted by academic researchers and authors. The necessary conditions for sending data and documents include 1. Sending an email to one of the researchers of the study 2. A brief and logical explanation regarding the use of data or documents. 3. Ensuring the registration of the protocol of systematic review studies that have requested access to data or documents. Community Verified icon

**From where data/document is obtainable**

By requesting the study researchers ZahraDarabi darabida4@gmail.com MaliheHadadnezhad m.hadadnezhad@yahoo.com Mehdi Khaleghi Mehdikhaleghi60@yahoo.com

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

The applicant can request details using the message sent by email within 7 to 10 days.

**Comments**