

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### The effect of minimal footwear on postural control during gait initiation in blind and sighted adolescents, with and without cognitive load

#### Protocol summary

##### Study aim

The effect of minimal footwear on postural control during gait initiation in blind and sighted adolescents, with and without cognitive load

##### Design

A quasi-experimental clinical trial, a control group, non-random allocation, and 20 patients.

##### Settings and conduct

This study, conducted at the IUMS School of Rehabilitation Science, will employ force plate data collection during dual-task and single-task conditions. In the single-task phase, to document the gait initiation for participants in both the blind and sighted groups, participants will first stand barefoot on the force plate. Standing will be in a free-standing, bipedal position with a stable posture. A verbal instruction will then be given to initiate movement (under three foot-covering conditions: barefoot, wearing conventional footwear, and wearing minimalist footwear) The dual-task phase will be created by combining the single-task with the second task, which involves reverse counting.

##### Participants/Inclusion and exclusion criteria

Eligibility The blind group must have a visual acuity (400/20), and blindness may be congenital or acquired, with a duration of at least three years. Participants aged 13 to 17 years and in good general health, with no motor or balance problems in either group. Exclusion - Musculoskeletal abnormalities (impair independent movement or balance, or limit ROM) - Presence of cognitive disorders. - Participant's refusal.

##### Intervention groups

The shift of the COP in blind adolescents in the test group and in sighted adolescents in the control group will be examined under three foot-covering conditions (barefoot, wearing conventional footwear, and wearing minimalist footwear). Both groups will be assessed on gait initiation with and without reverse counting, considered as the second task, using a force plate.

##### Main outcome variables

Spatio-temporal parameters of the center of pressure movement Impulse

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250830067050N1**

Registration date: **2025-11-03, 1404/08/12**

Registration timing: **prospective**

Last update: **2025-11-03, 1404/08/12**

Update count: **0**

##### Registration date

2025-11-03, 1404/08/12

##### Registrant information

##### Name

Zahra Rahimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3308 9985

##### Email address

zahra.rahimi670@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-11-11, 1404/08/20

##### Expected recruitment end date

2026-03-01, 1404/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

The effect of minimal footwear on postural control during gait initiation in blind and sighted adolescents, with and without cognitive load

## Public title

Investigation of the Effect of Footwear on Balance

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

For the blind group: Visual acuity less than 400/20 (56)  
For the blind group: Blindness congenital or acquired by age 3 years  
For the blind group: Age between 13 and 17 years  
For the blind group: General health and absence of motor or balance disorders  
For the sighted (control) group: Normal vision with no history of visual impairment  
For the sighted (control) group: Age between 13 and 17 years  
For the sighted (control) group: General health and absence of motor or balance disorders

### Exclusion criteria:

Musculoskeletal or neuromuscular abnormalities that would impair independent movement  
Any neuromuscular disease such as Parkinson's disease, cerebellar or vestibular disorders  
Neurological diseases associated with balance impairment  
Use of medications that disrupt walking or balance  
Presence of cognitive disorders as determined by the Neo personality questionnaire  
Limitation in the range of motion required for the hip, knee, and ankle joints for normal gait  
Lack of willingness to continue participation in the study

## Age

From **13 years** old to **17 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **20**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

In this study, blind adolescents will be assigned to the test group and sighted adolescents to the control group, and both groups will be assessed under identical conditions and with identical interventions. The objective of this study is to examine the impact of removing vision.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

research.ethics.iums

#### Approval date

2025-08-16, 1404/05/25

#### Ethics committee reference number

IR.IUMS.REC.1404.518

## Health conditions studied

### 1

#### Description of health condition studied

Blindness

#### ICD-10 code

H54.0

#### ICD-10 code description

Blindness, both eyes

## Primary outcomes

### 1

#### Description

Spatio-temporal parameters of the center of pressure during gait initiation

#### Timepoint

Immediate effect

#### Method of measurement

Force plate

### 2

#### Description

Impulse

#### Timepoint

Immediate effect

#### Method of measurement

Force plate and calculation

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Blind adolescents aged 13 to 17 years will be assessed under three foot conditions—barefoot, minimalist footwear, and conventional footwear—with and without a cognitive load (dual-task). The assessment will include measures of the center of pressure displacement and impulse at the initiation of the walking cycle.

#### Category

Rehabilitation

### 2

#### Description

Control group: Sighted adolescents aged 13 to 17 years will be assessed under three foot conditions—barefoot, minimalist footwear, and conventional footwear—with and without a cognitive load (dual-task). The assessment will include measures of the center of pressure displacement and impulse at the initiation of the walking cycle.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Iran University of Medical Sciences ,School of Rehabilitation Science

##### Full name of responsible person

Zahra Rahimi

##### Street address

Reza Faraji Alley, Shahabadi St., Piroozi

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### 2

#### Recruitment center

##### Name of recruitment center

Sport Sciences Research

##### Full name of responsible person

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Majid Safa

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5th Floor, Iran University of Medical Sciences, Hemmat Highway

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+98 21 8862 2703

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safa.m@iums.ac.ir

#### 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

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Zahra Rahimi

##### Position

Student

##### Latest degree

Master

##### Other areas of specialty/work

Orthosis and Prosthesis

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**Other areas of specialty/work**

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**Sharing plan**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

We do not have ethical approval for this purpose.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available