Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

City
Tehran

Province
Tehran

Postal code
1764685783

Phone
+98 21 3308 9985

Email
Zahra.rahimi670@gmail.com

2

Recruitment center

Name of recruitment center
Sport Sciences Research

Full name of responsible person
Zahra Rahimi

Street address
Reza Faraji Alley, Shahabadi St., Piroozi

City
Tehran

Province
Tehran

Postal code
1764685783

Phone
+98 21 3308 9985

Email
Zahra.rahimi670@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Majid Safa

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

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 8862 2703

Email
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

Street address
No. 19, 4th Floor, Reza Faraji Alley, Shahabadi Street, Piroozi Street, Tehran, Tehran Province, Iran

City
Tehran

Province
Tehran

Postal code
1764685783

Phone
+98 21 3308 9985

Fax

Email
zahra.rahimi670@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammad Ali Sanjari

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Biomechanics

Street address
School of Rehabilitation Science, Madakaran Alley, Shah Nazari Street, Mirdamad

City
Tehran

Province
Tehran

Postal code
۱۳۴۸۷ ۱۵۴۵۹

Phone
009822222095

Email
sanjarima@iums.ac.ir

Person responsible for updating data

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

Street address
No. 19, 4th Floor, Reza Faraji Alley, Shahabadi Street, Piroozi Street, Tehran, Tehran Province, Iran

City
Tehran

Province
Tehran

Postal code
1764685783

Phone
+98 21 3308 9985

Fax

Email
zahra.rahimi670@gmail.com

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