

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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)

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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

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Postal code

research.ethics.iuims

Approval date

2025-08-16, 1404/05/25

Ethics committee reference number

IR.IUIMS.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

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

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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

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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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