

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of toe-grip bar with arch support and Heel shoe flare on balance and gait in the old people

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Creating balance, optimal and stable gait in the elderly

Last update: **2021-05-30, 1400/03/09**

Update count: **0**

Design

In this study, by designing a insole with a protrusion under the toe and medial arch support and widening the heel of the shoe, we increase the balance and as a result, create a stable gait for the elderly. The sample size of 15 elderly people is in an intervention group and we do not have a control group.

Registration date

2021-05-30, 1400/03/09

Registrant information

Name

Alireza Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5053

Email address

taheri@rehab.mui.ac.ir

Settings and conduct

This study is performed in 15 Musculoskeletal Research Center of Isfahan University of Medical Sciences on 15 elderly people over 60 years old who have fallen at least once in the last 6 months and the parameters of gate and balance with medical insole intervention with shoes in these people by the device We will evaluate the gait analysis and force plate.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Conditions for entering the study: - Elderly over 60 years
- Has fallen at least once in the last 6 months Have the ability to walk independently inside and outside the home to perform daily activities. Conditions for not entering the study: People with neuromuscular diseases, diabetes, amputation History of surgery or fracture in the lower limb during the last ten years People taking balance medications

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

A group will receive an insole and shoes and we do not have a control group

Scientific title

The effect of toe-grip bar with arch support and Heel shoe flare on balance and gait in the old people

Main outcome variables

balance , gait

Public title

The effect of insole and shoe changes on the balance and gait of the elderly

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201212049687N2**

Registration date: **2021-05-30, 1400/03/09**

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly over 60 years falling at least once in the last 6 months the ability to walk independently inside and outside the home to perform daily activities

Exclusion criteria:

People with neuromuscular diseases such as MS and Parkinson's People with diabetes Those who have a history of surgery or fractures in the lower extremities during the last ten years Those who take drugs that upset the balance People with amputations

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

street hezar jrib, isfahan university of medical sciences , rehabilitation school

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-05-11, 1400/02/21

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.062

Health conditions studied

1

Description of health condition studied

Elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The ratio of the sample balance score to the standard score of the force plate device

Timepoint

Balance and gait measurements before and immediately after the intervention

Method of measurement

How to measure static stability and balance by the force plate device and evaluate the type of gait by the gait analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Gait and balance parameters are evaluated by medical insole intervention with shoes in these people. To assess the balance, the force plate will be calculated while standing. People are asked to first stand on the force plate with shoes without insoles for 60 seconds and then in the stage Second, repeat this test with shoes with external flare made of hard rubber and insole with protrusion under the toe and arc support made of soft poly foam. Each step will be repeated 5 times. In the next step, to evaluate the parameters of the gait, we ask the person to look at the face without distraction and try to walk in a straight line with constant speed and length of steps in the gate laboratory. This test is first with shoes and then It will be repeated 5 times with shoes and insoles.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

kashany hospital

Full name of responsible person

Alireza Taheri

Street address

street Hezar jrib, isfahan university of medical

sciences, rehabilitation school

City

Isfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۱

Phone

+98 31 3792 5053

Email

taheri@rehab.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Javanmard Haghjo

Street address

street Hezar jrib, isfahan university of medical sciences , rehabilitation school

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5053

Email

taheri@rehab.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Alireza taheri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

Street address

Street Hezar jrib, isfahan university of medical sciences , rehabilitation school

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5053

Email

taheri@rehab.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Alireza Taheri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

Street address

Street Hezar jrib, Isfahan university of medical sciences , rehabilitation school

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5053

Email

taheri@rehab.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Alireza Taheri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

Street address

Street Hezar jrib , Isfahan university of medical sciences, rehabilitation school

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5053

Email

taheri@rehab.mui.ac.ir

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

No - There is not 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

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