

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effects of textured insoles on the balance of older people with callus formation under the foot: a controlled study

Protocol summary

Study aim

To investigate the effects of textured insoles on the balance of older people with callus formation under the foot

Design

Clinical trial, parallel group design, with 30 participants

Settings and conduct

Participants were recruited from outpatient clinic in Alzahra hospital, Isfahan, Iran through a convenience sampling method.

Participants/Inclusion and exclusion criteria

Inclusion criteria were age over 60 years; Body mass index between 20 to 30; People with foot callus (grade 2 and 3); and the history of a fall in the last six months. Exclusion criteria included neurological and musculoskeletal conditions which affect the balance, vestibular dysfunction, and diabetes melitus.

Intervention groups

Interventions included textured and placebo insoles. The Placebo was a flat insole covered with a printed film only illustrated the textured pattern. A flat insole without any texture was used as the control condition. This insole has 3mm thickness the same as international insoles to occupy the same room in the shoes.

Main outcome variables

The primary outcome measures were the upright postural stability, ankle joint position sense, and timed-up and go test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021034N3**

Registration date: **2019-12-30, 1398/10/09**

Registration timing: **retrospective**

Last update: **2019-12-30, 1398/10/09**

Update count: **0**

Registration date

2019-12-30, 1398/10/09

Registrant information

Name

Ebrahim Sadeghi-Demneh

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-11, 1396/05/20

Expected recruitment end date

2018-01-10, 1396/10/20

Actual recruitment start date

2017-10-07, 1396/07/15

Actual recruitment end date

2018-05-31, 1397/03/10

Trial completion date

2018-05-31, 1397/03/10

Scientific title

The effects of textured insoles on the balance of older people with callus formation under the foot: a controlled study

Public title

Shoe inserts for elders with callus under the foot

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 60 years
Body mass index between 20 to 30
People with foot callus (grade 2 and 3)
People with the history of two falls in the last six months

Exclusion criteria:

People with neurological conditions (e.g. Parkinson's disease and multiple sclerosis)
Musculoskeletal conditions affect the balance
People with vestibular dysfunction
Having diabetes melitus

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethical committee of Isfahan University of Medical Sciences, Isfahan, Iran

Street address

Hezar Jerib St.

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8174673461

Approval date

2017-07-23, 1396/05/01

Ethics committee reference number

IR.MUI.REC.1396.3.252

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

Aging

ICD-10 code

L84

ICD-10 code description

Corns and callosities

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

Ankle Joint Position sense (proprioception)

Timepoint

All intervention was allocated in a straight forward session and outcomes were measured.

Method of measurement

Ankle proprioception was measured using perception of the inclination whilst participants stood over an adjustable slope box with closed eyes.

2**Description**

The mean velocity of center of pressure

Timepoint

All intervention was allocated in a straight forward session and outcomes were measured.

Method of measurement

Participant's Postural stability on the platform were be measured with mean velocity of CoP excursion in open and closed eye conditions. The duration of each test was 60 seconds. Each tests repeated 3 times and average reported.

3**Description**

Timed up and go test

Timepoint

All intervention was allocated in a straight forward session and outcomes were measured.

Method of measurement

The time required to get up from a chair, walking 3 meters, turning back, and sitting on the chair was recorded.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Using textured insole made with PVC that was in direct touch with the skin of the sole. This insole had 5mm diameter, 3mm height, and 10mm peak-to-peak distance circular projections.

Category

2**Description**

Intervention group: Placebo insole. The pattern of the projections on the textured insole was scanned and printed on a PVC (banner) film. This printed film was attached on a plain/flat insole with 3mm thickness then used in the study.

Category

Placebo

3**Description**

Control group: A flat insole without any texture. This insole has 3mm thickness the same as international insoles to occupy the same room in the shoes.

Category

Treatment - Devices

Recruitment centers1**Recruitment center****Name of recruitment center**

Alzahra Hospital, Isfahan, Iran

Full name of responsible person

Mohamad Saleki

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mahdi Nematbakhsh

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Grant name

Postgraduate studies' support

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

Ebrahim Sadeghi-Demneh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study data (excluding the personal details) can be shared with other researchers or systematic reviewers.

When the data will become available and for how long

No time limit is set.

To whom data/document is available

No specific limitation is considered.

Under which criteria data/document could be used

No terms and conditions is considered for sharing the data.

From where data/document is obtainable

People can send their request to the correspondence and obtain the data.

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

Request can be sent through an email.

Comments