

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effects of foot orthoses on balance, postural control and dynamic plantar pressure distribution in older adults with pronated foot-A randomized clinical control trial

Protocol summary

Study aim

Determination of the effect of foot orthoses on balance, postural control and dynamic plantar pressure distribution in older adults with pronated foot

Design

Present study is designed as a prospective, randomized-controlled parallel-group clinical trial.

Settings and conduct

En The research is conducted in the Shahrood city and participants are selected from the health centers of this city. Blinding is not done.

Participants/Inclusion and exclusion criteria

Inclusion criteria; Age over 65 years old; Confirmation of falling risk by falling screening algorithm; Pronated foot confirmation by foot posture index; Independent living in the community; Ability to walk without any help; and Medical certificate to participate in the study. Exclusion criteria; Institutional older adults; A history of depression, anxiety, or other mental disorders confirmed by GDS-15; Presence of neurological or musculoskeletal problems; Lower extremity prosthetics; Peripheral neuropathy or diabetes; Dementia confirmed by MMSE; Vision problem despite the glasses correction; and Previous use of foot orthosis

Intervention groups

Four types of commercial insoles are considered in this study; A) the soft insole (Shore A below 20) made of polyester and polyurethane sponge. B) Textured insoles, C) standard insoles (Shore A 25-30), and D) hard insoles (Shore A40-50), all made of polyester and ethylene vinyl acetate (EVA). The textured insole has convex circular beads with a center-to-center distance of approximately 10 mm. All insoles have heel cup with a height of approximately 15 mm, 25 mm arch support, and posting (the highest difference between the height of the inner and outer edges) is 15 mm. These insoles are designed and manufactured by Papaya Company.

Main outcome variables

Fear of falling ; Dynamic balance ; Static balance; Postural control; and Dynamic foot pressure distribution patterns.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170114031942N6**

Registration date: **2018-04-22, 1397/02/02**

Registration timing: **prospective**

Last update: **2018-04-22, 1397/02/02**

Update count: **0**

Registration date

2018-04-22, 1397/02/02

Registrant information

Name

Aynollah Naderi

Name of organization / entity

Shahrood University of Technology

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of foot orthoses on balance, postural control and dynamic plantar pressure distribution in older adults with pronated foot-A randomized clinical control trial

Public title

Effect of foot orthoses for older adults with pronated foot

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 65 years old Confirmation of falling risk by falling screening algorithm Pronated foot confirmation by foot posture index Independent living in the community Ability to walk without any help (for example, without a cane or walker) Medical certificate to participate in the study

Exclusion criteria:

Institutional older adults (nursing home and hospitalized) A history of depression, anxiety, or other mental disorders confirmed by GDS-15 Presence of neurological or musculoskeletal problems (such as a history of cardiovascular disease, Parkinson's disease, lower extremity surgery, significant orthopedic disorders or acute illness) Lower extremity prosthetics Peripheral neuropathy or diabetes Dementia confirmed by MMSE Vision problem despite the glasses correction Previous use of foot orthosis

Age

From **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are firstly enrolled by one of the research colleagues. An independent assessor, blinded person who has no further involvement in the study creates a random allocation sequence using a computer Software prior to the initiation of the study that use to randomize participants with 1:1 allocation ratio. A block randomization design (block size of 8) are applied to ensure an equal number of participants in each group. Group allocation are concealed in sequentially

numbered, opaque, sealed envelopes, and corresponding envelopes are opened after enrolled participants complete all baseline assessments.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of shahroud university of medical sciences

Street address

Seventh Tir Square, Shahroud

City

shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Approval date

2018-03-07, 1396/12/16

Ethics committee reference number

IR.shmu.REC.1396.194

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

Older adult health

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fear of falling

Timepoint

The fear of falling is measured before, immediately and 16 weeks after intervention.

Method of measurement

Fall Efficacy Scale International

2**Description**

Dynamic balance

Timepoint

Dynamic balance is measured before, immediately and 16 weeks after intervention.

Method of measurement

Dynamic gait index

3

Description

Static balance

Timepoint

Static balance is measured before, immediately and 16 weeks after intervention.

Method of measurement

Frailty and Injuries: Cooperative Studies of Intervention Techniques-4

4

Description

Postural control

Timepoint

Posture control is measured before, immediately and 16 weeks after intervention.

Method of measurement

Footscan pressure plat

5

Description

Dynamic foot pressure distribution patterns

Timepoint

Dynamic foot pressure distribution patterns is measured before, immediately and 16 weeks after intervention.

Method of measurement

Footscan pressure plat

Secondary outcomes

1

Description

Comfort of the orthoses

Timepoint

The comfort of the orthoses is measured immediately after the intervention and 1 week after the intervention.

Method of measurement

Comfort Index of Orthotic

Intervention groups

1

Description

Soft insole group: This group receives a soft insole with Shore A below 20 made of polyester and polyurethane sponge.

Category

Prevention

2

Description

Textured insole group: This group receives textured insole with Shore A25-30 made polyester and ethylene vinyl acetate (EVA).

Category

Prevention

3

Description

Standard insole group: This group receives standard insole with Shore A25-30 made polyester and ethylene vinyl acetate (EVA).

Category

Prevention

4

Description

Hard insole group: This group receives hard insole with Shore A25-30 made polyester and ethylene vinyl acetate (EVA).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrood city

Full name of responsible person

Aynollah Naderi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrood University of Technology

Full name of responsible person

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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

Shahroud University of Technology

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Hosein Ebrahimi

Street address

Shahroud, Seventh Tir Square, Shahroud University of Medical Sciences

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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

Shahroud University of Medical Sciences

Proportion provided by this source

50

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

Shahroud University of Technology

Full name of responsible person

Aynollah Naderi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physical Education and Sports Science

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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

No more information

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

No - There is not 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