

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparing the effect of medical insoles with Non-Slip Socks on balance and the fear of falling in the elderly

Protocol summary

Study aim

Determining the comparison of the effect of medical insoles with anti-slip socks on balance and fear of falling in the elderly

Design

The present study is a parallel controlled experimental study available on 60 elderly people. will be The people who enter the study are placed in 4 groups by permutation block randomization method. Sequentially numbered, sealed, opaque envelopes (SNOSE) are used in order to hide the allocation of participants to groups.

Settings and conduct

This study is conducted on the elderly of Shiraz city in 1401. For eligible seniors, the tests are taken once before the intervention and once after completing the intervention course (one month later).

Participants/Inclusion and exclusion criteria

Age condition: No history of falling resulting in damage to the lower limbs, Not using walking aids, Ability to walk without assistance at least up to 12 meters, and Not having any cognitive impairment or neurological or muscular disease! Unwillingness to continue attending the study, Orthopedic conditions that cause impaired walking or recent injuries, Occurrence of stressful events such as death and loss of family members, accidents or new acute illnesses, Unstable medical conditions and cognitive impairment, Acute psychiatric conditions or being treated for mental disorders

Intervention groups

The study includes 3 intervention groups (the elderly who use non-slip socks, the elderly who use insoles + normal socks, the elderly who use insoles + non-slip socks) and a control group (elderly with bare feet).

Main outcome variables

Falling, balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037576N5**

Registration date: **2022-10-26, 1401/08/04**

Registration timing: **prospective**

Last update: **2022-10-26, 1401/08/04**

Update count: **0**

Registration date

2022-10-26, 1401/08/04

Registrant information

Name

Mohammad Hadadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of medical insoles with Non-Slip Socks on balance and the fear of falling in the elderly

Public title

The effect of medical insole on elderly balance

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age conditions (60 years and above) No history of falls resulting in damage to the lower limbs No use of aids for walking Ability to walk without assistance at least up to 12 meters Not having any cognitive impairment or neurological or muscular disease(based on the MMSE test)

Exclusion criteria:

Reluctance to continue participating in the study Orthopedic conditions that cause walking disorders or recent injuries Occurrence of stressful events such as death and loss of family members, accidents or new acute diseases Unstable medical conditions and cognitive impairment Acute conditions Psychiatric or under treatment for mental disorders

Age

From 60 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals who enter the study are placed in 4 groups by permutation block randomization method. It should be noted that the examiners of this study are unaware of the steps of randomization and registration of participants and this will be done by another person.

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 Committees of Shiraz School of Rehabilitation Sciences

Street address

School of Rehabilitation Sciences Abiverdi 1 St. Chamran Blvd. Shiraz Iran

City

Shiraz

Province

Fars

Postal code

713451733

Approval date

2022-09-14, 1401/06/23

Ethics committee reference number

IR.SUMS.REHAB.REC.1401.029

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

Elderly

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

Balance

Timepoint

Before the intervention and one week after the end of the intervention

Method of measurement

TUG and BBS-9 and FAB tests in person during periodical examinations

2**Description**

Fear of falling

Timepoint

Before the intervention and one week after the end of the intervention

Method of measurement

FES-I short questionnaire in person during periodical examinations

Secondary outcomes

empty

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

Intervention group: Group 1: There are 15 people in this group, and the fear of falling questionnaire and TUG, BBS-9, FAB tests are taken. Then, this group will be given a model of anti-slip socks with silicone soles. The use of socks can affect the contact friction of the foot with the ground surface and by catching the slip of the heel, it can maintain balance. Then they are asked to wear said socks at home for a month. After one month, the above tests will be taken again from the group and the

questionnaires will be completed and the results will be compared before and after.

Category

Diagnosis

2

Description

Intervention group: Group 2: There are 15 people in this group, and the fear of falling questionnaire and TUG, BBS-9, and FAB tests are taken. Then this group will be given a normal sock model + textured insole. Textured insoles provide sensory input to the entire foot area and provide tactile stimulation to plantar mechanoreceptors created by ridges on the surface of the insoles, which increase attention and sensory input in the sole. They are then asked to Wear said socks at home for one month. After one month, the above tests will be taken again from the group and the questionnaires will be completed and the results will be compared before and after.

Category

Diagnosis

3

Description

Intervention group: Group 3: There are 15 people in this group, and the fear of falling questionnaire and TUG, BBS-9, FAB tests are taken. Then this group will be given a non-slip sock model with a silicone sole + insole. Using socks can affect the contact friction of the foot with the ground surface and help maintain balance by catching the slip of the heel. Also, insoles increase attention and sensory input in the soles of the feet and can increase the stability of the standing position of young and elderly people in blindfolded conditions. Then, they are asked to wear the said insole socks at home for a month. After one month, the above tests will be taken again from the group and the questionnaires will be completed and the results will be compared before and after.

Category

Diagnosis

4

Description

Control group: Group 4: Due to the fact that the elderly spend considerable time at home and their common footwear at home is socks, sandals or bare feet, as a result, the control group of this study is the elderly with bare feet. There are 15 people in this group, and the fear of falling questionnaire and TUG, BBS-9, FAB tests are taken. After one month, the above tests will be taken again from the group and the questionnaires will be completed and the results will be compared before and after.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz university of medical sciences

Full name of responsible person

Dr. Mohammad Haddadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Haddadi

Street address

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Grant name

Grant code / Reference number

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

No

Title of funding source

Shiraz 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

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Contact

Name of organization / entity
Shiraz University of Medical Sciences
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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