Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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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+98 71 3627 1551

Email address
hadadim@sums.ac.ir

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

Street address

Abiverdi St

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

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?

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

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Fatemeh Razmjouie

Position
Masters student

Latest degree
Master

Other areas of specialty/work
Geriatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr. Mohammad Haddadi

Position
Associate Professor

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Other areas of specialty/work
Others

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Fatemeh razmjouie

Position
Masters student

Latest degree
Master

Other areas of specialty/work
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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