

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effectiveness of Non-Slip Socks on Balance Control, Fear and Prevention of Fall in Older Female Members of the Farzanegan Foundation at Home: A Parallel RCT

Protocol summary

Study aim

Increase balance and prevent falls in elderly women

Design

A randomized clinical trial on 42 people, using an equal block randomization method, unblinded, sample size is 250 with equal sample size in 6 parallel groups (4 intervention groups and 2 control groups).

Settings and conduct

Balance tests are performed in the Farzangan Foundation of Shiraz with the presence of the presenter and the clinic manager.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Elderly women 60-74 years; No history of falls leading to injury to the limb; Do not use aids to walk; Ability to walk without assistance for at least 12 meters; Do not have any cognitive impairment or neuromuscular disease Having a normal TUG. Exclusion criteria: Reluctance to attend the study; Orthopedic conditions that cause recent gait impairment or injury; Occurrence of stressful events such as death and loss of family members, accident or new illness; Unstable medical conditions and cognitive impairment; Acute psychiatric conditions or under treatment for mental disorders.

Intervention groups

study has 4 intervention groups(seniors who use 4 models of anti-slip socks) and 2 control groups(seniors with bare feet and seniors who use sandals)

Main outcome variables

Balance; fall rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180514039648N4**

Registration date: **2022-07-05, 1401/04/14**

Registration timing: **retrospective**

Last update: **2022-07-05, 1401/04/14**

Update count: **0**

Registration date

2022-07-05, 1401/04/14

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-06-19, 1401/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Non-Slip Socks on Balance Control, Fear and Prevention of Fall in Older Female Members of the Farzanegan Foundation at Home: A Parallel RCT

Public title

The effect of anti-slip socks on maintaining balance, panic and preventing falls in elderly Shirazi women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

- Age requirements (60-74 years) Gender condition (female age) Willingness to participate in the study No history of falls leading to injury to the limb Do not use aids to walk Ability to walk without assistance at least 12 meters Do not have any cognitive impairment or neuromuscular disease (based on the observation and self-expression of the person and also using the personal file in the Farzanegan Foundation) Having a normal TUG

Exclusion criteria:

Reluctance to attend the study Orthopedic conditions that cause recent gait impairment or injury Occurrence of stressful events such as death and loss of family members, accident or new illness Unstable medical conditions and cognitive impairment Acute psychiatric conditions or under treatment for mental disorders (reported by the elderly person and based on his / her file in Farzanegan Farhizgan Foundation)

Age

From **60 years** old to **74 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

In this parallel trial, at first, 250 elderly people who meet the inclusion criteria were selected and they were asked to complete the fear of falling questionnaire and we performed the TUG balance tests and Berg balance scale for them, and the elderly people whose fear of falling was scored 28-16 means that they have a fear of falling and normal balance, they are selected as samples. Every elderly person in Farzangan Foundation has an ID, and 42 people with their own ID were selected as the main sample and a demographic questionnaire was completed for them. With the membership number in Farzangan Foundation and registering the numbers in the software, which completely randomly places each number in a group, 42 people are selected from the 250 people who have the conditions and are distributed in equal blocks in the groups. Using Efron's equal block randomization using PASS version 15 software (the output of this software is presented as a table of random numbers that divides the sample into equal groups with equal chance and distribution of equal blocks) The sample is divided into 6 equal groups (7 people) (equal blocks is used with the aim of creating a balance in the number of samples allocated to each of the groups under study and an equal number of people are placed in all blocks) that 2 The group is selected as the control group and 4 groups as the experimental group. In other words, in order to

randomize the generated groups and allocate them to the intervention and control groups, the software has been assigned a membership code in the Farzangan Foundation and randomly with equal blocks.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

According to the quarterly review of the situation of companies producing and importing socks available in the Iranian market, 4 categories of socks with different designs have been advertised and identified as anti-slip socks for the elderly, pregnant women, medical staff and sports clubs. Also, by examining the physical mobility of the elderly at home in general, it was found that they work in this environment in two ways without bare feet (barefoot) with leather sandals. Therefore, this study is based on 4 models of socks, 4 groups of experimental groups and 2 groups as a control group (without cover and with sandals).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz university of medical sciences

Street address

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Postal code

7153675541

Approval date

2022-04-09, 1401/01/20

Ethics committee reference number

IR.SUMS.SCHEANUT.REC.1401.019

Health conditions studied

1

Description of health condition studied

nil.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fall

Timepoint

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

Method of measurement

Berg balance test and TUG test in person during periodical examinations

2

Description

Maintain balance in the elderly

Timepoint

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

Method of measurement

Berg balance test and TUG test in person during periodical examinations

3

Description

Reduce the fear of falling in the elderly

Timepoint

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

Method of measurement

Short version of the fear of falling questionnaire(FES-I) in person during periodical examinations

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group 1: There are 6 people in this group who, after completing the questionnaire of fear of falling and performing balance and BERG balance tests, are given anti-slip socks of the first type, which is made of leather socks. The use of socks can affect the friction of the foot in contact with the ground, and in addition, due to the importance of the heel, anti-slip socks can try to help maintain balance by catching the heel slip. Then they are asked to use this type of sock at home for 2 months. After 2 months, they will be taken again from the group of balance tests, BERG balance tests and the questionnaire of fear of falling will be completed for them and the results will be compared before and after.

Category

Diagnosis

2

Description

Intervention group: Group 2: There are 6 people in this group who, after completing the questionnaire of fear of

falling and performing balance and BERG balance tests, are given anti-slip socks of the second type, which is made of silicone socks. The use of socks can affect the friction of the foot in contact with the ground, and in addition, due to the importance of the heel, anti-slip socks can try to help maintain balance by catching the heel slip. Then they are asked to use this type of sock at home for 2 months. After 2 months, they will be taken again from the group of balance tests, BERG balance tests and the questionnaire of fear of falling will be completed for them and the results will be compared before and after.

Category

Diagnosis

3

Description

Intervention group: Group 3: There are 6 people in this group who, after completing the questionnaire of fear of falling and performing balance and BERG balance tests, are given anti-slip socks of the third type, which is made of compressed plastic socks. The use of socks can affect the friction of the foot in contact with the ground, and in addition, due to the importance of the heel, anti-slip socks can try to help maintain balance by catching the heel slip. Then they are asked to use this type of sock at home for 2 months. After 2 months, they will be taken again from the group of balance tests, BERG balance tests and the questionnaire of fear of falling will be completed for them and the results will be compared before and after.

Category

Diagnosis

4

Description

Intervention group: Group 4: There are 6 people in this group who, after completing the questionnaire of fear of falling and performing balance and BERG balance tests, are given anti-slip socks of the second type, which is made of silicone socks. The use of socks can affect the friction of the foot in contact with the ground, and in addition, due to the importance of the heel, anti-slip socks can try to help maintain balance by catching the heel slip. Then they are asked to use this type of sock at home for 2 months. After 2 months, they will be taken again from the group of balance tests, BERG balance tests and the questionnaire of fear of falling will be completed for them and the results will be compared before and after.

Category

Diagnosis

5

Description

Control group: Group 1: The elderly spend a considerable amount of time at home, and the most common covering at home is socks, sandals, or bare feet. There are 6 people in this group who, after completing the questionnaire on fear of falling and performing balance

and BERG balance tests, are not given special socks in this group and are asked to walk around the house barefoot. 2 months again, a balance sheet will be taken from the group of balance tests, BERG balance tests and a fall fear questionnaire will be completed for them, and the results will be compared before and after.

Category

Other

6**Description**

Control group: Group 2: The elderly spend a considerable amount of time at home, and the most common covering at home is socks, sandals, or bare feet. There are 6 people in this group who, after completing the questionnaire on fear of falling and performing balance and BERG balance tests, are not given special socks in this group and are asked to walk around in their sandals at home. 2 months again, a balance sheet will be taken from the group of balance tests, BERG balance tests and a fall fear questionnaire will be completed for them, and the results will be compared before and after.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

07137251001

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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

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Email

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

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

Title and more details about the data/document

In the process, data is collected.

When the data will become available and for how long

It takes about 1 month to collect data from the elderly under the auspices of the Foundation of Educated Scholars.

To whom data/document is available

People under the auspices of the Foundation of Educated Scholars

Under which criteria data/document could be used

Age requirements (60-74 years) Gender condition (elderly woman) No history of falls leading to limb damage

From where data/document is obtainable

Educated Scholars Foundation of Shiraz

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

Samples are collected by performing equilibrium tests and classifying them.

Comments