

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Aug 2026

### The effect of stepping on fall prevention program, on quality of life, fear of fall, and fall related behaviors of the elderly people

#### Protocol summary

##### Study aim

Determining the effect of stepping on fall prevention program o quality of life, Fear of fall, and fall related behaviors in the elderly people referred to Selected health care centers in Shiraz

##### Design

This is a clinical trial study with a parallel control group, uses single blinding. The study population has been consisted of all elderly people referring to selected health centers in Shiraz. The sample size with considering 14% attrition rate, are 50 in each group. Samples are divided into two intervention and control groups with randomized block assignment with 4-block permutations.

##### Settings and conduct

After approving the plan at Shiraz University of Medical Sciences and receiving the relevant codes, all seniors who are referred to the relevant clinics are invited to participate in the research. The training content of the crash prevention program consists of 7 training sessions of 60-90 minutes. Meetings are held in groups in the conference room of selected clinics. Each session covers different aspects to reduce the risk of falling. After the intervention and two months after the intervention, the questionnaires were again filled in two groups.

##### Participants/Inclusion and exclusion criteria

Participants are the elderly who refer to selected health care centers, are aware of the time, place, and person, have not known mental illness, and are able to walk and not miss more than two training sessions.

##### Intervention groups

The intervention group participates in the 7 sessions of fall stepping on program, and the control group receives only routine care.

##### Main outcome variables

The independent variable is the stepping on fall prevention program and dependent variables are includes of quality of life, fear of fall and fall related behaviors.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190506043498N1**

Registration date: **2019-12-08, 1398/09/17**

Registration timing: **retrospective**

Last update: **2019-12-08, 1398/09/17**

Update count: **0**

##### Registration date

2019-12-08, 1398/09/17

##### Registrant information

##### Name

Mrayam Ebrahimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3620 1328

##### Email address

maryameb1374@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-05-22, 1398/03/01

##### Expected recruitment end date

2019-06-22, 1398/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The effect of stepping on fall prevention program, on quality of life, fear of fall, and fall related behaviors of the elderly people |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Public title</b>                                                                                                                   | the effect of stepping on fall prevention program, on quality of life, fear of fall, and fall related behaviors of the elderly people                                                                                                                                                                                                                                                                                                                                     |
| <b>Purpose</b>                                                                                                                        | Prevention                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Inclusion/Exclusion criteria</b>                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Inclusion criteria:</b>                                                                                                            | Older people who came to the health care centers because of a disease or follow up willing to participate in the study be aware of time and place and person Able to walk independently                                                                                                                                                                                                                                                                                   |
| <b>Exclusion criteria:</b>                                                                                                            | attending in similar previous studies a known case of mental illness Those who die during the study or do not continue the study process Those who fill the questionnaire incompletely Absence of more than 2 sessions at training sessions                                                                                                                                                                                                                               |
| <b>Age</b>                                                                                                                            | From <b>60 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Gender</b>                                                                                                                         | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Phase</b>                                                                                                                          | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Groups that have been masked</b>                                                                                                   | <ul style="list-style-type: none"> <li>Participant</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Sample size</b>                                                                                                                    | Target sample size: <b>100</b>                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Randomization (investigator's opinion)</b>                                                                                         | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Randomization description</b>                                                                                                      | In this study, the subjects were randomly assigned to intervention and control groups by blocked randomization. At first, the permutations of the four blocks are numbered. Then, randomly, the number of permutations is selected and the ordering of individuals in groups is recorded in a table.                                                                                                                                                                      |
| <b>Blinding (investigator's opinion)</b>                                                                                              | Single blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Blinding description</b>                                                                                                           | In this study, only the participants in the study are unaware of which group they are located.                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Placebo</b>                                                                                                                        | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Assignment</b>                                                                                                                     | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Other design features</b>                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Secondary Ids</b>                                                                                                                  | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Ethics committees</b>                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b><u>1</u></b>                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Ethics committee</b>                                                                                                               | <p><b>Name of ethics committee</b><br/>Ethics committee of Shiraz University of Medical Sciences</p> <p><b>Street address</b><br/>7th Floor, Central Building of Shiraz University of Medical Sciences, Zand Blvd, Shiraz, Iran</p> <p><b>City</b><br/>shiraz</p> <p><b>Province</b><br/>Fars</p> <p><b>Postal code</b><br/>713451978</p> <p><b>Approval date</b><br/>2019-01-23, 1397/11/03</p> <p><b>Ethics committee reference number</b><br/>IR.SUMS.REC.1398.038</p> |
| <b>Health conditions studied</b>                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b><u>1</u></b>                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Description of health condition studied</b>                                                                                        | fall                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>ICD-10 code</b>                                                                                                                    | Z91.81                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>ICD-10 code description</b>                                                                                                        | History of falling                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b><u>2</u></b>                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Description of health condition studied</b>                                                                                        | fear of fall                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>ICD-10 code</b>                                                                                                                    | F40.233                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>ICD-10 code description</b>                                                                                                        | Fear of injury                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b><u>3</u></b>                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Description of health condition studied</b>                                                                                        | quality of life                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>ICD-10 code</b>                                                                                                                    | Z73                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>ICD-10 code description</b>                                                                                                        | Problems related to life management difficulty                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b><u>4</u></b>                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Description of health condition studied</b>                                                                                        | fall related behaviors in elderly people                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>ICD-10 code</b>                                                                                                                    | W19                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>ICD-10 code description</b>                                                                                                        | Unspecified fall                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Primary outcomes</b>                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b><u>1</u></b>                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Description</b>                                                                                                                    | Fear of fall                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Timepoint</b>                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

Before the intervention, immediately after the intervention and two months later.

**Method of measurement**

Falls Efficacy Scale

**2**

**Description**

Quality of life

**Timepoint**

Before the intervention, immediately after the intervention and two months later.

**Method of measurement**

Lipad Quality of Life Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Intervention group will participate in 7 training sessions of the stepping-on fall training program. Sessions are held in groups in the conference room of selected clinics for 90-60 minutes. Each session covers various aspects of risk factors for falls and ways to prevent them such as home modification, medication management, exercise and other related factors.

**Category**

Prevention

**2**

**Description**

Control group: receive routine care. However, at the end of the study, the educational content of the stepping-on educational program was provided to the control group in the format of the DVD

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emam Reza clinic

**Full name of responsible person**

Maryam Ebrahimi

**Street address**

Namazi Square, Zand Blvd. Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

71348714737

**Phone**

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**2**

**Recruitment center**

**Name of recruitment center**

Motahari polyclinic

**Full name of responsible person**

Maryam Ebrahimi

**Street address**

Motahari polyclinic, Namazi Sq, Shiraz, Fars Province

**City**

Shiraz

**Province**

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**Postal code**

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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**

Dr. Younes Ghasemi

**Street address**

7th Floor, Shiraz University of Medical Sciences, Zand Street, Shiraz

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Shiraz

**Province**

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**Postal code**

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**Phone**

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**Email**

vcrdep@sums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Maryam Ebrahimi

**Position**

Student in geriatric nursing at master level

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Fatemeh(PBUH) Nursing and Midwifery School,  
Namazee Square, Shiraz, Iran

**City**

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**Province**

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**Fax****Email**

maryameb1374@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Sakineh Gholamzadeh

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Geriatrics

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Fatemeh Nursing and Midwifery School, Namazee  
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**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Maryam Ebrahimi

**Position**

Student in geriatric nursing at master level

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Fatemeh Nursing and Midwifery School, Namazee  
Square

**City**

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**Province**

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**Phone**

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**Email**

maryameb1374@gmail.com

**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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

A portion of the information, such as data on the main  
outcome can be shared.

**When the data will become available and for how long**

Access to data is available 6 months after the publication  
of the results

**To whom data/document is available**

Researchers working in academia and scientific  
institution

**Under which criteria data/document could be used**

Data will be used for similar study scientifically and with  
reference. To access the data, they can email the  
respondent

**From where data/document is obtainable**

You can contact: maryameb1374@gmail.com

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

Applicants can email the respondent and receive an  
answer within a week.

**Comments**

In case of non-response, please send a second email