

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The Effect of Equilibrium Exercises on the Effectiveness of Fear of Falling and Preventing Crashes in the Elderly

#### Protocol summary

##### Study aim

The aim of this study was to investigate the The Effect of Equilibrium Exercise on the Effectiveness of Fear of Falling and Preventing Crashes in the Elderly 60-75 Years Old Woman in Lenjan City

##### Design

From the four health centers of Zarrin Shahr, the names of the two health centers are selected in lottery and used to extract the intervention samples using the electronic health record software, and from the remaining two remaining health centers are used to extract the control group. The number of samples in each group was 35.

##### Settings and conduct

The goal of the study is to investigate elderly women referring to health centers in Zarrinshahr, who are afraid of falling while taking care of the modern health services of the elderly. Then, the target population was randomly divided into two groups of test and control groups (lotteries of health centers names).

##### Participants/Inclusion and exclusion criteria

Women ages 60 to 75; Individual Satisfaction and Marital Satisfaction; Certified physician to participate in the exercise program; Self-report fear of falling during care Inability to perform Equilibrium exercises under medical supervision; Unwillingness to participate in the study; Absence of more than 1 session during Equilibrium exercises; Participation in exercise sessions outside intervention program; Hospitalization due to acute illness or injury; People with diabetes; People with depression

##### Intervention groups

Intervention group: This group receives a batch of physical exercises called Equilibrium exercises for 8 weeks each week for 2 sessions and each session for 1 hour (totaling 16 hours) under the supervision of a sports expert. Control group: This group, without knowledge of the intervention, intervenes in their normal care and life at the health center and does not exercise any activity

##### Main outcome variables

Effectiveness of Fear of Falling and Falling (fall down)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180216038754N1**

Registration date: **2018-04-05, 1397/01/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-05, 1397/01/16**

Update count: **0**

##### Registration date

2018-04-05, 1397/01/16

##### Registrant information

##### Name

Raheleh Soleymani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5262 6525

##### Email address

lenjan-health@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-03, 1397/01/14

##### Expected recruitment end date

2018-05-04, 1397/02/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Equilibrium Exercises on the Effectiveness of Fear of Falling and Preventing Crashes in the Elderly

**Public title**

Falling in older adults

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Women ages 60 to 75 Individual Satisfaction and Marital Satisfaction Certified physician to participate in the exercise program Self-report fear of falling during care

**Exclusion criteria:**

Inability to perform Equilibrium exercises under medical supervision Unwillingness to participate in the study Absence of more than 1 session during Equilibrium exercises Participation in exercise sessions outside intervention program Hospitalization due to acute illness or injury People with diabetes People with depression

**Age**

From **60 years** old to **75 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **35**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

From the four health centers of Zarrin Shahr, the names of the two health centers are selected in lottery and used to extract the intervention samples using the electronic health record software, and from the remaining two remaining health centers are used to extract the control group. By referring to the health centers, the elderly healthcare electronic health records are reviewed first, then the elderly who questioned whether they are afraid of falling? Positive answers are listed, then they are Simple randomization selected from the list of odd's numbers and, if satisfied, are enrolled in the study.

**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 Isfahan University of Medical Sciences

**Street address**

International Bureau, Isfahan University of Medical Sciences, P.O. Box 319, Hezar-Jerib Ave., Isfahan, IR Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2017-12-31, 1396/10/10

**Ethics committee reference number**

IR.MUI.REC.1396.1.152

**Health conditions studied**

1

**Description of health condition studied**

Fear of falling

**ICD-10 code**

40.9

**ICD-10 code description**

Phobic anxiety disorder, unspecified

2

**Description of health condition studied**

Fall down

**ICD-10 code**

W00-W19

**ICD-10 code description**

Fall on same level from slipping, tripping and stumbling

**Primary outcomes**

1

**Description**

Effectiveness of fear of falling

**Timepoint**

Before the intervention, one month after the intervention, three months after the intervention

**Method of measurement**

Efficiency Scale Questionnaire for Elderly

**Secondary outcomes**

1

**Description**

Fall down

**Timepoint**

Before the intervention, one year after the intervention

**Method of measurement**

Care Questionnaire of fall and imbalances

## Intervention groups

### 1

#### Description

Intervention group: This group receives a batch of physical exercises called Equilibrium exercises for 8 weeks each week for 2 sessions and each session for 1 hour (totaling 16 hours) under the supervision of a sports expert.

#### Category

Rehabilitation

### 2

#### Description

Control group: This group, without knowledge of the intervention, intervenes in their normal care and life at the health center and does not exercise any activity.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health centers in Lenjan city

##### Full name of responsible person

Rahele Soleimani

##### Street address

Family Health Unit, Health Center in Lenjan, Shariati St., Zarin Shahr

##### City

Zarin Shar

##### Province

Isfahan

##### Postal code

8471754749

##### Phone

+98 31 5223 2545

##### Email

lenjan-health@mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Amir Mohammad Armanian

##### Street address

No. 4, Hezargarib st, Isfahan University of Medical Sciences

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 8138

##### Email

lenjan-health@mui.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Raheleh Soleymani

##### Position

Health Family Health Network Expert

##### Latest degree

Master

##### Other areas of specialty/work

Health Promotion

##### Street address

Shariati St. Langian Health Center

##### City

Zarinshahr

##### Province

Isfahan

##### Postal code

8471754749

##### Phone

+98 31 5262 6525

##### Fax

##### Email

raheel\_s59@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Raheleh Soleymani

##### Position

Health Family Health Network Expert

##### Latest degree

Master  
**Other areas of specialty/work**  
Health Promotion  
**Street address**  
Shariati St. Langian Health Center  
**City**  
Zarinshahr  
**Province**  
Isfahan  
**Postal code**  
8471754749  
**Phone**  
+98 31 5262 6525  
**Fax**  
**Email**  
raheel\_s59@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Raheleh Soleymani  
**Position**  
Health Family Health Network Expert  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Health Promotion  
**Street address**  
Shariati St. Langian Health Center

**City**  
Zarinshahr  
**Province**  
Isfahan  
**Postal code**  
8471754749  
**Phone**  
+98 31 5262 6525  
**Fax**  
**Email**  
raheel\_s59@yahoo.com

## 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

No - There is not 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

Not applicable

### 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