

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Effectiveness of short -term Conditional-Equilibrium Exercises on Functional Limitations of fear of falling in Aged Women with Frailty Syndrome

#### Protocol summary

##### Study aim

Effectiveness of short -term Conditional-Equilibrium Exercises on Functional Limitations of fear of falling in Aged Women with Frailty Syndrome in Shiraz Farzanegan Foundation

##### Design

Controlled clinical trial parallel Randomized

##### Settings and conduct

Individuals are divided into intervention and control groups. For the intervention group, 6 training sessions are held every week for 6 weeks with the subject of situational-balance exercises. While there will be no intervention in the control group.

##### Participants/Inclusion and exclusion criteria

1. Over 55 years old 2. Having at least 3 items from the frailty Index 3. Earn at least 21 points on the leaf test 4. Earn at least 22 points from the Fear of the Fall and Movement Restriction Questionnaire 5. No orthopedic and neurological disorders 6. No severe visual and auditory impairment

##### Intervention groups

Conditional-Equilibrium Exercises training to women with frailty syndrome in experimental group Lack of Conditional-Equilibrium Exercises training in women with Frailty syndrome in the control group

##### Main outcome variables

Improved fear of falling, functional limitations, and reduced frailty consequences.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180514039648N1**  
Registration date: **2020-07-07, 1399/04/17**  
Registration timing: **retrospective**

Last update: **2020-07-07, 1399/04/17**

Update count: **0**

##### Registration date

2020-07-07, 1399/04/17

##### Registrant information

###### Name

Abdolrahim Asadollahi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3725 1001

###### Email address

a\_asadollahi@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-08, 1398/09/17

##### Expected recruitment end date

2020-02-06, 1398/11/17

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of short -term Conditional-Equilibrium Exercises on Functional Limitations of fear of falling in Aged Women with Frailty Syndrome

##### Public title

The effect of balance exercises on women with Frailty syndrome

##### Purpose

Prevention

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Over 55 years old  
Having at least 3 items from the Frailty Index  
No orthopedic and neurological disorders  
No Severe visual and auditory impairment  
Earn at least 22 points on the survey of activities and fear of falling Questionnaire

### **Exclusion criteria:**

## **Age**

From **55 years** old

## **Gender**

Female

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **120**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

The randomly assigned by equal permutation blocks method using PASS 11 (2017) software. Effron method was performed one thousand times and according to this method, despite the randomization of the allocation process, individuals in each block were finally provided with equal number of samples in both control and intervention groups. In randomization, an equal chance is provided for the whole sample to fall into one of two groups. The researcher does not intervene in determining the group for the samples.

## **Blinding (investigator's opinion)**

Not blinded

## **Blinding description**

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

The samples were randomly divided into control and experimental groups. The experimental group then receives training based on short-term Conditional-Equilibrium Exercises on Functional Limitations of fear of falling. not receive any intervention during the training.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Faculty of Rehabilitation Sciences, Shiraz University of Medical Sciences

##### **Street address**

Abbeyvard Street 1, Chamran Boulevard,shiraz

##### **City**

shiraz

## **Province**

Fars

## **Postal code**

۳۳۶۶۹-۷۱۹۴۷

## **Approval date**

2019-12-08, 1398/09/17

## **Ethics committee reference number**

IR.SUMS.REHAB.REC.1398.035

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

frailty syndrom

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### **1**

#### **Description**

Frailty

#### **Timepoint**

At the beginning and immediately after the intervention is completed

#### **Method of measurement**

FSC,5 Item ,2001

### **2**

#### **Description**

Fear of falling and activity restriction

#### **Timepoint**

At the beginning and immediately after the intervention is completed

#### **Method of measurement**

The survey of activities and fear of falling in the elderly (SAFE)

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The central intervention in this study was a situational-equilibrium short-term training program. The training program was based on the general content of the exercise, which aims to "improve functional limitations due to the fear of falling in elderly women with frailty syndrome using short-term situational-equilibrium exercises." The treatment program used in this study is in accordance with the official and standard protocol of "Prevention and safety techniques in falling for the elderly" (Team, 2014), which actually improves muscle strength, increases coordination and flexibility and maintains a state of

stability, stability and They become physically balanced, and the exercises were performed in the supine, posterior, side, four-legged, and standing positions. The exercises are designed to be graded and, at the discretion of the therapist and the physical condition of the elderly, can be made more difficult or easier during sessions or even unchanged. According to Rina's standard studies, Benazar and Diaz will be practiced for a short period of time, for 6 weeks and 2 sessions a week for 1 hour and in groups. Prior to the intervention, short training sessions on fall conditions and compensatory techniques required during the fall, as well as the correct posture of the subjects during the training sessions, the correct angle of the joints and the correct way to walk, sleep and sit. During the sessions, they will be reminded regularly as a reminder. One session will be held to familiarize the participants with how to do the exercises and how to hold the training sessions. Educational media such as PowerPoint presentations, video educational video clips, and educational pamphlets will be used for teaching.

**Category**

Rehabilitation

**2****Description**

Control group: No special training will be provided for the control group.

**Category**

Rehabilitation

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

Shiraz Farzanegan Foundation

**Full name of responsible person**

Mrs.Tahereh sokout

**Street address**

mirza shirazi Ave. front of 8 th.st

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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**

Seventh floor, Central Building of Shiraz University of Medical Sciences, Zand Avenue, Shiraz

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**Province**

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7134814336

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**Fax**

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**Email**

vcrdep@sums.ac.ir

**Web page address**

<http://research.sums.ac.ir/fa/index.html>

**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**

Dr. Abdolrahim Asadollahi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Geriatrics

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Abdolrahim Asadollahi

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

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

The data file will be shared in Mendeley's database in the form of spss software version 25.

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

2020

**To whom data/document is available**

faculty members of schools of health and Rehabilitation , Shiraz University of Medical Sciences

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

more study

**From where data/document is obtainable**

Researchers

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

Send official email

**Comments**