

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

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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

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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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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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Full name of responsible person

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Person responsible for updating data

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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