

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

The Effect of Frenkel Exercises on gait disturbance and Fear of Fall in Aged Patients with balance disorders: A Parallel Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of Frankel exercise on gait disturbance and fear of falling in the elderly with balance disorder

Design

A clinical trial with a control group, with parallel groups, randomized on 100 patients, rand function of Excel software was used for randomization.

Settings and conduct

The elderly will be selected based on the researcher's criteria and by sequential sampling method in Tasua Babol clinic and will be grouped into blocks of 4 based on the randomization software and then will be assigned to the intervention group and the control group. Patients exercise for 30 minutes five days a week for six weeks.

Participants/Inclusion and exclusion criteria

Entry requirements: Age over 65 years, Having a confidential family caregiver between 18 and 60 years old, According to the results of the Romberg test, have balance problems, Having independence based on the KATZ Basic ADL questionnaire (a person enters the study with a score of 5 or 6. Non-entry conditions: Cognitive impairment based on the MMSE questionnaire, a person with a score of 18 and above is included in the study, Regularly or irregularly used sports for balance during the last six months, Existence of medical contraindications to exercise, such as chest pain, shortness of breath, extreme fatigue, severe muscle and joint pain, disability, deformity, and heart palpitations. The presence of destructive progressive neurological disorders such as dementia and Parkinson's that interfere with the ability to exercise.

Intervention groups

In the intervention group, balance exercises are used according to Frenkel's exercises, which include learning how to turn, sit and stand up using different everyday objects such as a chair, bed, or painted footprints on the floor. In the control group, routine care is applied.

Main outcome variables

Fear of Fall; gait disturbance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056554N1**

Registration date: **2023-01-07, 1401/10/17**

Registration timing: **prospective**

Last update: **2023-01-07, 1401/10/17**

Update count: **0**

Registration date

2023-01-07, 1401/10/17

Registrant information

Name

Hamed Salahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 9699

Email address

hamedsalahi9776@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-15, 1401/10/25

Expected recruitment end date

2023-01-30, 1401/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Placebo Not used
Scientific title The Effect of Frenkel Exercises on gait disturbance and Fear of Fall in Aged Patients with balance disorders: A Parallel Randomized Clinical Trial	Assignment Parallel
	Other design features
Public title Effect of Frenkel Exercises in aged patients with balance disorders	Secondary Ids empty
Purpose Supportive	Ethics committees
Inclusion/Exclusion criteria Inclusion criteria: Age over 65 years Having a confidential family caregiver between 18 and 60 years old According to the results of the Romberg test, have balance problems Having independence based on the KATZ Basic ADL questionnaire (a person enters the study with a score of 5 or 6) Exclusion criteria: Cognitive impairment based on the MMSE questionnaire, a person with a score of 18 and above is included in the study Regularly or irregularly used exercise for balance during the last six months Existence of medical contraindications to exercise, such as chest pain, shortness of breath, extreme fatigue, severe muscle and joint pain, disability, heart beat and deformity The presence of destructive progressive neurological disorders such as dementia and Parkinson's that interfere with the ability to exercise	1 Ethics committee Name of ethics committee Ethics committee of Shahroud University of Medical Sciences Street address Shahroud University of Medical Sciences, 7th Blvd, Shahroud City Shahroud Province Semnan Postal code 3614773943 Approval date 2022-12-10, 1401/09/19 Ethics committee reference number IR.SHMU.REC.1401.183
Age From 65 years old	Health conditions studied
Gender Both	1 Description of health condition studied Balance disorder ICD-10 code ICD-10 code description
Phase N/A	Primary outcomes
Groups that have been masked No information	1 Description The score of Fear of fall in Falls Efficacy Scale-International Timepoint Measuring the fear of falling at the beginning of the study (before the intervention) and at the end of the study (the day after the last training session) Method of measurement Falls Efficacy Scale-International
Sample size Target sample size: 110	2 Description The score of gait disorder in Timed Up and Go test Timepoint Measurement of walking disorder at the beginning of the study (before the start of the intervention) and at the
Randomization (investigator's opinion) Randomized	
Randomization description Based on the randomization software, the elderly will be grouped in blocks of 4 and will be placed in two groups A and B, and then the letter A will be randomly assigned to the intervention group and the letter B will be assigned to the control group. The required sequence for allocating patients to 2 groups (intervention group and control group) will be done through randomization and based on the generation of numbers through the software (randomizer). The order of randomization will be done in secret, that is, 82 envelopes will be prepared in the package, in each of which there will be code A and B. After it is determined that the target person participates in the study, the researcher takes the target envelope in the specified order and takes action based on the group registered in the envelope.	
Blinding (investigator's opinion) Not blinded	
Blinding description	

end of the study (the day after the last training session)

Method of measurement

Timed Up and Go test

Secondary outcomes

1

Description

Changes in personal medication use

Timepoint

at the beginning of the study (before the start of the intervention) and at the end of the study (one day after the last training session)

Method of measurement

Personal characteristics questionnaire

Intervention groups

1

Description

Intervention group: Frankel's balance exercises are used, which include learning how to walk with the upper limbs and learning how to turn, sit and stand up using various everyday objects such as a chair, a bed or painted footprints on the floor.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tasua super special clinic

Full name of responsible person

Mohammad reza vesgar

Street address

In front of Imam Hassan Mosque, Shahid Bazzaz Ave

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Mazandaran

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4717665764

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr.Mohammad Hasan Emamian

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Shahroud university of medical sciences, 7th Tir Blvd,
Shahroud Town

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Semnan

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Phone

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info@shmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Hamed Salahi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Not applicable

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Release as thesis

When the data will become available and for how long

Six months after defending the thesis

To whom data/document is available

Researchers working in academic and scientific institutions, people working in industry

Under which criteria data/document could be used

It will be accessible by submitting an application to the university

From where data/document is obtainable

Hamed Salahi, project manager

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

Submit their request via email

Comments