

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of Otago exercises and chair squat under supervision at home on the fear of falling and the quality of life of the elderly referring to Rafsanjan comprehensive health centers in 2023.

Protocol summary

Study aim

Determining the comparative effect of the effect of Otago exercises and chair squat under supervision at home on the fear of falling and the quality of life of the elderly.

Design

120 eligible seniors will be divided into 3 groups (two intervention groups and one control group) using a simple random division method using a random number table, and the type of intervention will be determined again by random division.

Settings and conduct

The intervention will done on elderly with fear of falling and low quality of life referring to Rafsanjan health centers. Both interventions will done at home by Individuals.

Participants/Inclusion and exclusion criteria

Entry criteria: over 60 years old, score of 10 from the SAFFE questionnaire, low average quality of life based on the SF-36 questionnaire, not having a severe hearing and vision problems and physical and mental problems that prevent movement, not having to diseases and the use of drugs that cause balance disorders and fear of falling, complete mastery of the Persian language, not living in Nursing home or other institutions, not having an activity prohibition order from a doctor, not having a disability. Exit criteria: unwillingness to continue cooperation, not doing more than 3 sessions of training, suffering from physical diseases that prevent full participation in training.

Intervention groups

Both intervention groups with one of their family members participates in an orientation session and the protocol of each exercise in each group is taught by the researcher using handbook and videos. then for 8 weeks, 3 sessions of 45 minutes per week at home they exercises according to the training method. control

group do their usual daily activities. Fear of falling and quality of life of all participants in the study will be measured before and one month after the end of the intervention.

Main outcome variables

Fear of falling, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150519022320N29**

Registration date: **2023-07-21, 1402/04/30**

Registration timing: **prospective**

Last update: **2023-07-21, 1402/04/30**

Update count: **0**

Registration date

2023-07-21, 1402/04/30

Registrant information

Name

Tayebeh Mirzaei

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Otago exercises and chair squat under supervision at home on the fear of falling and the quality of life of the elderly referring to Rafsanjan comprehensive health centers in 2023.

Public title

Comparison of the effect of Otago exercises and chair squat under supervision at home on the fear of falling and the quality of life of the elderly.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being over 60 years old Obtaining an average score of 10 from the SAFFE questionnaire Having a low average quality of life based on the SF-36 questionnaire Not having a severe hearing problem Not having severe vision problems Not having physical and mental problems that prevent movements Not suffering from diseases such as stroke, dementia, multiple sclerosis, orthopedic problems, as well as taking medications that cause balance disorders and fear of falling (obtaining information through interviews and examining the health status of the elderly) Complete mastery of the Persian language Not living in a nursing home or other institutions Not having an activity prohibition order from the doctor No having disability

Exclusion criteria:

History of spine fracture and vertebral and orthopedic problems Having a regular exercise program in the previous 6 months Having health problems affecting doing exercises at home such as heart disorder, brain disorder, dyspnea, arrhythmia Chronic use of knee braces, crutches, walkers and wheelchairs

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

After determining the samples, the data will be divided into 3 groups A, B, and C according to age and sex, in such a way that the first data in one of the 3 groups will be divided by a simple random method and using the "Random allocation software" are selected and and in

the next 2 groups, the data is allocated in the same way based on the software. After allocating the data equally to 3 groups, treatment methods were written on 3 separate sheets and a method will be assigned to each group by lottery, and the intervention groups of Otago exercise and Chair Squat exercise and the Control group will be determined.

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**

Research Ethics Committee of Rafsanjan University of Medical Sciences

Street address

School of Nursing and Midwifery, Nurse Avenue, Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2023-07-19, 1402/04/28

Ethics committee reference number

IR.RUMS.REC.1402.051

Health conditions studied**1****Description of health condition studied**

Fear of falling

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Quality of Life

ICD-10 code**ICD-10 code description****Primary outcomes**

1

Description

elderly Fear of falling

Timepoint

All participants will complete the SAFFE fear of falling questionnaire before and one month after the end of the intervention.

Method of measurement

SAFFE fear of falling questionnaire

2

Description

elderly quality of life

Timepoint

All participants will complete the SF-36 quality of life questionnaire before and one month after the end of the intervention.

Method of measurement

SF-36 Quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Otago exercise intervention group with one of their family members participates in an orientation session and the exercise protocol is taught by the researcher using training handbook and videos, and at the end of the session, all the elderly are assessed one by one in terms of correct performance of exercises. Then, for 8 weeks, 3 sessions a week and each session lasts 45 minutes at home, they do Otago exercises according to the training method. During the study, all the participants are monitored through virtual groups in which the elderly themselves or one of their family members who attended the briefing session are members, as well as telephone follow-ups, and they can raise their questions and problems. Each session exercises is reminded and monitored, and if possible, training videos of the exercises are also shared for them.

Category

Treatment - Other

2

Description

Intervention group: The Chair squat exercise intervention group with one of their family members participates in an orientation session and the exercise protocol is taught by the researcher using training handbook and videos, and at the end of the session, all the elderly are assessed one by one in terms of correct performance of exercises. Then, for 8 weeks, 3 sessions a week and each session lasts 45 minutes at home, they do Chair squat exercises according to the training method. During the study, all the participants are monitored through virtual

groups in which the elderly themselves or one of their family members who attended the briefing session are members, as well as telephone follow-ups, and they can raise their questions and problems. Each session exercises is reminded and monitored, and if possible, training videos of the exercises are also shared for them.

Category

Treatment - Other

3

Description

Control group: In the control group with the same conditions as the intervention groups, there is no intervention and they continue their usual daily activities.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rafsanjan comprehensive health centers

Full name of responsible person

Dr.Tayebeh Mirzaei, KHalil Abadi

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Faculty of Nursing, Nurse Blvd., Jomhury street, Rafsanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.Tayebeh Mirzaei, KHalil Abadi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

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