

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Effect of exercise on balance status and quality of life among sample of Iranian elderly in Shiraz, south of IRAN, 2017

Protocol summary

Study aim

In order to teach the effect of equilibrium exercises on improving balance and improving the quality of life in elderly people in Shiraz, it will be done

Design

Initially, the two main daily aging centers were selected by random sampling method (milk and line) in the experimental and control groups and individuals using the goal-oriented method from among the clients participating in the training programs of the mentioned centers and then by random allocation of the block Equal to the experimental (30) and control (30) groups

Settings and conduct

After identifying the test and control group, the researcher begins to evaluate the subjects through various tests and, after the end of the assessment, begins the training instructor.

Participants/Inclusion and exclusion criteria

Include criteria: Falling over the past 6 to 12 months
Exclude criteria: Unwillingness to cooperate

Intervention groups

Cawthorne-cooksey training for two weeks each week is provided to the experimental group, during which the experimental group will receive no training. At the end of the study, the control group will be presented to the control group for observing the ethics of the training sessions.

Main outcome variables

Improve balance, quality of life and reduce the frequency of falls

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180730040644N1**

Registration date: **2018-08-15, 1397/05/24**

Registration timing: **retrospective**

Last update: **2018-08-15, 1397/05/24**

Update count: **0**

Registration date

2018-08-15, 1397/05/24

Registrant information

Name

Farzaneh Bahadori

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

2017-10-23, 1396/08/01

Actual recruitment end date

2017-11-21, 1396/08/30

Trial completion date

empty

Scientific title

Effect of exercise on balance status and quality of life among sample of Iranian elderly in Shiraz, south of IRAN, 2017

Public title

Effect of exercise on balance status and quality of life among sample of Iranian elderly in Shiraz, south of IRAN, 2017

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

age (60- 74 years) basic literacy (ability to read and write), history of falling over the past 6-12 months positive Romberg sign obtaining minimum score 24 in the mini-mental state examination (MMSE) obtaining minimum score 21in Berg Balance Scale (BBS) lack of visual impairment lack of neck disability non-use of ambulatory assistive devices (AAD) lack of cognitive impairment and lack of orthopedic and neural impairments

Exclusion criteria:

Unwillingness to continue cooperation incidence of musculoskeletal disorders requiring the use of ambulatory assistive devices or needing treatment.

Age

From **60 years** old to **74 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, the clients referring to two main daily care ageing centers were randomly (via coin flipping) assigned to the experimental and control groups in order to prevent data transmission between the participants in both groups. A total of 60 older people (30 individuals from each center) were selected using the goal-based approach from the clients participating in the educational programs of these two centers

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand Street, opposite Palestine Street, Central Building of Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

۱۴۳۳۶ - ۷۱۳۴۸

Approval date

2018-01-15, 1396/10/25

Ethics committee reference number

IR.SUMS.REC.1396.142

Health conditions studied

1

Description of health condition studied

Disorders of vestibular function Fall in the elderly

ICD-10 code

H81.8X1

ICD-10 code description

Other disorders of vestibular function, right ear

Primary outcomes

1

Description

The Effect of Balanced Exercise Training to Improve Balance and Quality of Life in the Elderly

Timepoint

At the beginning of the intervention (before the study began) and immediately after the completion of the study and 2 months after the end of the study

Method of measurement

VNG, BBS.DHI.FES-I,Romberg,Leipad Test

Secondary outcomes

1

Description

To determine and compare the effect of equilibrium training on improving balance and improving the quality of life before and after intervention in two groups of test and control

Timepoint

At the beginning of the study (before the start of the study), immediately after the end of the intervention and 2 months after the last training sessions

Method of measurement

assess the effect of equilibrium training on improving balance (BBS and Roemberg questionnaires) and quality of life (Leipad)

2

Description

Evaluating the effect of equilibrium exercise training on reducing the number of falls in the elderly

Timepoint

At the beginning of the study (before the start of the study), immediately after the end of the intervention and 2 months after the last training sessions

Method of measurement

Evaluating the effect of equilibrium exercise training on reducing the frequency of falls (taking patient records and performing BBS and Römberg tests)

Intervention groups

1

Description

Intervention group: Conducting training courses that include Cawthorne Cooksey (to improve the Vestibular system) and deep-seated strengthening exercises (including tensile and strength exercises)

Category

Rehabilitation

2

Description

Control group: After the intervention in the intervention group, a training session entitled "Equal Exercise Exercise" was provided to the control group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Soroush's Elderly Center

Full name of responsible person

Tahreh Sokut

Street address

Mirza Shirazi Blvd. - 16 m Dinakan facing Alavi Park

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad-Hosseini Kaveh

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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

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

Farzaneh Bahadori

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Geriatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad-Hosseini Kaveh

Position

Associate Professor, Faculty Member of Shiraz

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Ph.D.

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Person responsible for updating data

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Full name of responsible person

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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

Yes - There is 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

Not applicable

Title and more details about the data/document

Only final analysis and data file initialization

When the data will become available and for how long

Time to print the article up to a year later

To whom data/document is available

All researchers

Under which criteria data/document could be used

There is no manipulation in the data

From where data/document is obtainable

Send a request by email, if not answered, phone call

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

The requested time is about a week after the request is
sent

Comments