

# 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)

###### Phone

+98 71 3824 8333

###### Email address

bahadori\_farzaneh@yahoo.com

##### 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

##### City

Shiraz

##### Province

Fars

##### Postal code

71776-73548

##### Phone

+98 71 3635 1362

##### Email

af\_sokout@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Mohammad-Hosseini Kaveh

##### Street address

Razi Blvd. School of Public Health

##### City

Shiraz

##### Province

Fars

##### Postal code

7762514751

##### Phone

+98 71 3725 1005

##### Email

Schealth@sums.ac.ir

#### 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

##### Street address

Razi Blvd. School of Public Health

##### City

Shiraz

##### Province

Fars

##### Postal code

7756245321

##### Phone

+98 71 3725 1001

##### Email

bahadori\_farzaneh@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Mohammad-Hosseini Kaveh

##### Position

Associate Professor, Faculty Member of Shiraz

University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Razi Blvd. School of Public Health

**City**

Shiraz

**Province**

Fars

**Postal code**

77415724120

**Phone**

+98 71 3725 1001

**Email**

kaveh@sums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammad-Hossein Kaveh

**Position**

Associate Professor, Faculty Member of Shiraz  
University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Razi Blvd. School of Public Health

**City**

Shiraz

**Province**

Fars

**Postal code**

7741253461

**Phone**

+98 71 3725 1001

**Email**

kaveh@sums.ac.ir

**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**