Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

The comparison of the effects of physical activity and neurofeedback training on postural stability and risk of fall in elderly women: a double-blind randomized controlled trial

Protocol summary

Summary

(1) Objectives The aim of this study is to compare the effects of physical activity and neurofeedback training on postural stability and risk of fall in elderly women. (2) Design (study groups and phase, sample size, blinding, randomization, single or multi center) This is a double-blind randomized controlled trial. 45 women will be recruited from one center. Participants are randomly (closed envelop with the name of the assigned group) divided into three groups including control, physical activity and neurofeedback training (15 per group). (3) Setting and conduct Fereshtegahn Elderly care center in Shiraz (4) Participants including major eligibility criteria 45 physically independent women who are older than 65 years old and in appropriate health status will be recruited. Older adults who are advanced in age (> 85 years) and at high risk for falls, participants with injury-related fall within past six months, and those who are suffering from a medical condition, such as musculoskeletal impairments, cardiovascular problems, and declines in sensory functioning and cognitive capabilities, or other neurological disease are excluded from the study. (5) Intervention Participants in exercise group will train the Kavern and Cooksey training protocol for 12 weeks (3 days per week and 30 minutes per each session). Another experimental group will perform the Neurofeedback intervention protocol that has been defined by Hammond in 2005 under the name of balance protocol (reduction of theta wave frequency in 4-7 Hz and reinforcement of beta wave frequency in 15-18 Hz) in the same duration and frequency. (6) main outcome measures (primary and secondary outcome variables) The Biodex Balance System is going to be used to assess the main outcomes of the study that include risk of fall and postural stability. The training and assessment will be performed with 2 different persons to be sure that there would not be any bias in the evaluation. Analysis of covariance is applied to determine the effects of interventions on outcome variables while controlling the effects of pre test scores.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071235037N1**
Registration date: **2017-08-22, 1396/05/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-22, 1396/05/31

Registrant information

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Recruitment status

Recruitment complete

Funding source

myself

Expected recruitment start date

2017-07-20, 1396/04/29

Expected recruitment end date

2017-09-20, 1396/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effects of physical activity and neurofeedback training on postural stability and risk of fall in elderly women: a double- blind randomized controlled trial

Public title

Exercise and Neurofeedback Intervention for improving postural stability and reducing risk of fall in elderly women.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: female, physically independent, appropriate health status, older than 65 years Exclusion: Older adults who are advanced in age (> 85 years) and at high risk for falls, participants with injury-related fall within past six months, those who are suffering from an acute medical condition, or have a chronic condition or a history of stroke and other neurological disease are excluded from the study. Furthermore, participants are withdrawn if they suffer a medical condition, such as musculoskeletal impairments, cardiovascular problems, and declines in sensory functioning and cognitive capabilities, during the study period that affect their ability to perform the tests.

Age

From **65 years** old to **85 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Faculty of Sport Science, Kharazmi University

Street address

Kharazmi University, Faculty of Sport Science, MirDamad, Razan, Keshvari sport complex

City

Tehran

Postal code

Approval date

2017-06-28, 1396/04/07

Ethics committee reference number

KHU.SS.4-1-6-2017

Health conditions studied

1

Description of health condition studied

not applicable

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

risk of fall

Timepoint

before intervention- 3 months after intervention

Method of measurement

biodex balance system

2

Description

postural stability

Timepoint

before intervention- 3 months after intervention

Method of measurement

biodex balance system

Secondary outcomes

empty

Intervention groups

1

Description

physical activity

Category

Rehabilitation

2

Description

neurofeedback training

Category

Rehabilitation

3

Description

control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fereshteghan Elderly Care Center

Full name of responsible person

Ayoub Hashemi

Street address

Shiraz, Amir Kabir Boulvar, Meysam Boulvar, East Soroush St. Second alley, right hand, Fereshtegan elderly care center

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

shahnaz shahrbanian

Full name of responsible person

shahnaz shahrbanian

Street address

amir abad shomali, n 15

City

tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

shahnaz shahrbanian

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Bou Ali Sina University/ Tehran University

Full name of responsible person

Shahnaz Shahrbanian

Position

Assistant professor/ phd

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty