

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Effect of eight weeks of square stepping training on fall risk factors in elderly men: a clinical trial study

Protocol summary

Study aim

The effect of performing eight weeks of square stepping exercises on the electrical activity of selected muscles and the risk of falling in elderly men.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 30 samples. It was used to randomize the sealed envelopes.

Settings and conduct

1. 30 elderly people aged 60-75 years were selected from the society according to the entry criteria and divided into two groups of 15 people for square stepping exercises and control. 2. Measurements related to the pre-test were carried out in Shahid Beheshti University laboratory. 3. The exercise group performed the protocol of the square stepping exercise program for 8 weeks, 3 sessions a week and each session lasted 60 to 70 minutes in the gym, and in parallel, the control group was asked to do any regular exercise and intervention during this period, refrained from sports and only engaged in daily activities, and in the last stage, measurements related to the post-test were performed and the results were reviewed and evaluated.

Participants/Inclusion and exclusion criteria

1. Elderly in the age range of 60 to 75 years; 2. Not being prohibited from medical activity (especially severe imbalance and dementia problems) under the supervision of a doctor; 3. Lack of regular sports activity in the last 6 months; 4. Not having a physical and cognitive prohibition to do exercises; 5. Completing the informed consent form and 6. Willingness to participate in research

Intervention groups

Two groups of 15 people square stepping and control exercises.

Main outcome variables

Evaluation of the exercise program and its effects on the risk of falls in the elderly and the electrical activity of related muscles.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230124057206N1**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

Name

Mohammad javad Nezhadmohammadi

Name of organization / entity

Shahid beheshti un

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-06, 1402/10/16

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of eight weeks of square stepping training on fall risk factors in elderly men: a clinical trial study

Public title

The effect of 8-week implementation of a balance exercise program called square stepping on the risk factors of falling in elderly men

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly in the age range of 60 to 75 years not prohibiting medical activity (especially severe imbalance and dementia problems) under the supervision of a doctor
Lack of regular sports activity in the last 6 months
Not having a physical and cognitive prohibition to do exercises
Completing the informed consent form
Willingness to participate in research

Exclusion criteria:

Age

From **60 years** old to **75 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are selected by simple randomization method. In this randomization method, all the samples have an equal chance to be selected, for this purpose, the samples are placed in the list of the statistical population prepared for this purpose, and a number is assigned to each of them, then the numbers are written on pieces of paper. It is written and folded and placed in a container, then it is removed by a third party as grains and it repeats until we reach the desired number.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is explained to the participants what program they are participating in and for what purpose, but how the results of this study will be reviewed and who the other research groups are and what program they may follow. It is not said to do. The clinical caregiver is the only clinical caregiver, there is no need to fully explain the conditions and the participants and the way of their intervention to him. The same goes for the rest of the roles.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کارگروه اخلاق در پژوهش پژوهشگاه علوم ورزشی

Street address

No. 3, Fifth Alley, Mir Emad St, Shahid Motahari St, Tehran

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tehran

Province

Tehran

Postal code

1587958711

Approval date

2023-12-20, 1402/09/29

Ethics committee reference number

IR.SSRC.REC.1402.278

Health conditions studied

1

Description of health condition studied

fall risk

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

fall risk

Timepoint

Before and eight weeks after the intervention

Method of measurement

Biodex device fall risk test

2

Description

Electromyography of selected muscles

Timepoint

Before and eight weeks after the intervention

Method of measurement

Megawin brand electromyography device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: square stepping exercise, this exercise program consists of walking on a pre-made grid of squares, which can be drawn either on the floor or on a portable thin mat. This grid is divided into 40 squares of 25x25, so the dimensions of the grid are 100x250. Stepping patterns are leveled in the exercise booklet. First, the pattern selected by the instructor is performed, then the participants perform the same algorithm to master. The participants must move from the beginning of the grid and according to the stepping pattern towards the end of the grid. Then, leaving the network, they would go back to the starting point from the right side of it and repeat the patterns. After people have mastered the training pattern, we ask them to raise their heels so that they do not touch the square lines. The pattern is repeated even individually. Then the next pattern is explained. In general, 196 training patterns have been designed based on the level of difficulty and progress in 8 categories (beginner 1 and 2, intermediate 1, 2 and 3 and advanced 1, 2 and 3). This training program lasts 8 weeks, three days a week and each session lasts 60 to 70 minutes. At the beginning of the exercise, about 15 minutes of warming up, then 40 minutes spent on exercise, and then about 15 minutes for cooling down are considered.

Category

Prevention

2

Description

Control group: performing daily activities in parallel, this group is asked to refrain from any regular exercise and sports intervention during this period of eight weeks and only engage in daily activities.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

vaght-e-zendegi center of Comprehensive services daily taking care of elderly

Full name of responsible person

zohreh ashouri

Street address

South Dibaji St., in front of Gerhani, the center of vaght-e-zendegi

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Email

m.nezhadmohammadi@mail.sbu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

shahid beheshty University

Full name of responsible person

seiiedeh mehri hamidi sangdehi

Street address

daneshjoo blvd, velenjak, tehran

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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

shahid beheshty University

Proportion provided by this source

30

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

shahid beheshty University

Full name of responsible person

mohammadjavad nezhadmohammadi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
shahid beheshti university of tehran
Full name of responsible person
zareei mostafa
Position
Associate professor
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data file without the name and information of the person, the raw sample of the informed consent form, the clinical study report is given in the text of the thesis.

When the data will become available and for how long

After the defense of the thesis, up to six months after that

To whom data/document is available

All people

Under which criteria data/document could be used

Any tampering with the data and misuse and plagiarism of them without mentioning the source is not allowed.

From where data/document is obtainable

data bases

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

serch on data bases

Comments