

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of the effect of home-based balance training exercise on balance indices of older adults

Protocol summary

Study aim

Evaluation of the effect of home-based balance training exercise on balance indices of older adults

Design

Two parallel group randomized by Permuted block randomization, designed for 50 elderly and blinded outcome

Settings and conduct

It is a randomized clinical trial that is conducted in Imam Reza Army Hospital in Tehran in 1401. In this study, 50 elderly people who refer to Imam Reza Hospital in Tehran in 1401 are randomly selected. After giving the necessary explanations, a signed written consent is obtained. Then the patients are put through the Timed up and go test, the 6 Minute Walk Test. Then patients are placed in one of two control groups or experimental groups. The control group walks thirty minutes a day, five days a week. The experimental group is trained in motor control exercises first, then, in addition to walking five days a week for 12 weeks, they also do exercises three times a week at home. Before the intervention, immediately after the completion of the treatment sessions and three months after the completion of the sessions, the patients are examined in terms of the mentioned factors.

Participants/Inclusion and exclusion criteria

elderly more than 60 years old independent ambulation use of cane or other assistive devices established Diabetes mellitus established neurologic disease severe cardiovascular disease severe peripheral vascular disease any disease preventing participation in more than 30% of training sessions

Intervention groups

Intervention group: walking 30 minutes per day, 5 days per week plus motor control exercise at home, 3 times per week for 12 weeks Control group: walking 30 minutes per day, 5 days per week

Main outcome variables

Timed up and go test 6 minutes walking test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220620055228N1**

Registration date: **2022-08-30, 1401/06/08**

Registration timing: **prospective**

Last update: **2022-08-30, 1401/06/08**

Update count: **0**

Registration date

2022-08-30, 1401/06/08

Registrant information

Name

Zahra Ahmadi Mottaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6653 0059

Email address

zahra.ahmadimottaghi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of home-based balance training exercise on balance indices of older adults

Public title

Evaluation of the effect of home-based balance training exercise on elderly's balance

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Elderly more than 60 years old Independent ambulation

Exclusion criteria:

Use of cane or other assistive devices Established Diabetes mellitus Established neurologic disease Severe cardiovascular disease Severe peripheral vascular disease Any disease preventing participation in more than 30% of training sessions Unwillingness to continues Not having at least two regular physical activity sessions per week

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

First, blocks of 6 are prepared, each block includes 3 patients for the control group and 3 patients for the intervention group. For example, in one block, the first three patients may be placed in the control group and the next three patients in the intervention group. And in another block, the patients may be divided one by one.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the intervention and control groups have an exercise program, but they do not know the difference between the program. The statistical analyst does not know the results.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of AJA University of Medical Sciences

Street address

AJA university of medical science, Etemadzade Ave, West Fatemi Blvd, Amirabad

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2022-06-20, 1401/03/30

Ethics committee reference number

IR.AJAUMS.REC.1401.003

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

elderly

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Timed up and go test

Timepoint

Before intervention, just after intervention, 3 months later

Method of measurement

Time required for standing, walking 3 meters, returning, go back and sitting

2**Description**

6 minutes walking test

Timepoint

Before intervention, just after intervention, 3 months later

Method of measurement

Distance of walking in 6 minutes

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: walking 30 minutes per day, 5 days per week

Category

Lifestyle

2

Description

Intervention group: walking 30 minutes per day, 5 days per week plus motor control exercise at home, 3 times per week for 12 weeks

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Zahra Ahmadi Mottaghi

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Imam Reza hospital, Etemadzadeh Ave, West Fatemi Blvd, Amirabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

رضا مساعد

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Zahra Ahmadi Mottaghi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Position

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Person responsible for updating data

Contact

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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