Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effect of Eight Weeks of Square Stepping with Otago Exercise on Motor and Cognitive Performance, Quality of Life and Fear of Falling in Older Adults with Mild Cognitive Impairment

Protocol summary

Study aim
Comparison of the Effect of Eight Weeks of Square Stepping with Otago Exercise on Motor and Cognitive Performance, Quality of Life and Fear of Falling in Older Adults with Mild Cognitive Impairment

Design
Participants will be selected using purposive sampling from nursing home residents aged 60 years and older with Mild Cognitive Impairment. They will then be randomly assigned to two groups of 15 participants each.

Settings and conduct
Older adults aged 60 years and above with Mild Cognitive Impairment residing in nursing homes will be recruited. After meeting the inclusion and exclusion criteria and completing the informed consent form and personal information questionnaire, participants will be randomly assigned, using simple randomization, to two groups of 15 participants each. One group will perform (SSE), while the other group will perform (OEP). Both interventions will be conducted for eight weeks, three sessions per week, with each session lasting 60 minutes.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:1)Older adults with Mild Cognitive Impairment (MCI).2)Age 60 years and older.3)Not concurrently participating in any other exercise or intervention program.4)Ability to understand instructions and complete the study questionnaires.5)Ability to participate in the physical assessments and perform physical activity. Exclusion Criteria:1)Absence from the training sessions.2)Presence of visual impairments that cannot be corrected by glasses, contact lenses, or surgery.3)Presence of any neurological disease, orthopedic disorder, or cardiovascular disorder.

Intervention groups
Group 1: Square-Stepping Exercise(SSE) Group 2: Otago Exercise Program(OEP)

Main outcome variables
lower limb strength, static balance, dynamic balance, gait speed, range of motion, functional independence, cognitive performance, quality of life, and fear of falling

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260609069721N1**
Registration date: **2026-06-12, 1405/03/22**
Registration timing: **prospective**

Last update: **2026-06-12, 1405/03/22**
Update count: **0**

Registration date
2026-06-12, 1405/03/22

Registrant information

Name
Reyhane Jalali
Name of organization / entity
The University of Isfahan
Country
Iran (Islamic Republic of)
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+98 31 3680 0000
Email address
reyhanejalali7636@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-13, 1405/03/23

Expected recruitment end date
2026-06-15, 1405/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Eight Weeks of Square Stepping with Otago Exercise on Motor and Cognitive Performance, Quality of Life and Fear of Falling in Older Adults with Mild Cognitive Impairment

Public title

Comparison of the Square Stepping with Otago Exercise on Motor and Cognitive Performance, Quality of Life and Fear of Falling in Older Adults with Mild Cognitive Impairment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1- Older adults with mild cognitive impairment, defined as a score between 19 and 26 on the Montreal Cognitive Assessment (MoCA). 2-Aged 60 years and older 3- Not concurrently participating in any other exercise or intervention program 4-Ability to understand instructions and complete the study questionnaires. 5- Ability to attend the physical assessments and participate in the study's physical activity program.

Exclusion criteria:

Unwillingness to continue participation in the study or attend the training sessions. Presence of visual impairments that cannot be corrected with glasses, contact lenses, or surgery. Presence of any neurological disease (e.g., stroke, Parkinson’s disease), orthopedic disorder (e.g., rheumatoid arthritis, bone fracture), or cardiovascular disorder.

Age

From **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the eligible participants and obtaining informed consent, participants were randomly assigned to the two intervention groups. For randomization, a unique identification code was assigned to each participant, and a random number was generated for each individual using the RAND function in Microsoft Excel. Participants were then ranked according to the generated random numbers and allocated equally to the Square-Stepping Exercise group and the Otago Exercise Program group (15 participants in each group).

Blinding (investigator's opinion)

Double blinded

Blinding description

Outcome assessments were conducted by an assessor who was unaware of the participants' group allocation. To minimize assessment bias, the assessor was blinded to the type of intervention received by the participants (Square-Stepping Exercise or the Otago Exercise Program). In addition, participants were unaware of the main study hypothesis and any potential superiority of one intervention over the other.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University

Street address

Research Ethics Committee, Third Floor, Central Library Building, University of Isfahan, University Street, Azadi Square, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

۸۱۷۴۶۷۳۴۴۱

Approval date

2026-05-04, 1405/02/14

Ethics committee reference number

IR.UI.REC.1405.028

Health conditions studied

1

Description of health condition studied

Comparison of the Effect of Eight Weeks of Square Stepping with Otago Exercise on Motor and Cognitive Performance, Quality of Life and Fear of Falling in Older Adults with Mild Cognitive Impairment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Lower limb strength will be assessed using the 30-Second Chair Stand Test. In this test, the participant is

asked to repeatedly stand up from and sit down on a standard chair without armrests for 30 seconds. The total number of completed sit-to-stand repetitions performed within 30 seconds will be recorded as the participant's score.

Timepoint

Time points of assessment for lower limb strength: Baseline (before intervention) and at the end of the study (after intervention).

Method of measurement

Lower limb strength will be assessed using the 30-Second Chair Stand Test.

2

Description

Static balance will be assessed using the Sharpened Romberg Test. In this test, participants will stand barefoot in a tandem position, with the dominant foot placed in front of the other foot and the arms crossed over the chest. The length of time that each participant is able to maintain balance in this position will be recorded as the test score.

Timepoint

Time points of assessment for static balance: Baseline (before intervention) and at the end of the study (after intervention).

Method of measurement

Static balance will be assessed using the Sharpened Romberg Test.

3

Description

Dynamic balance will be assessed using the Timed Up and Go (TUG) Test. In this test, participants will be instructed to sit on a chair and, upon the command “Go,” stand up, walk a distance of 3 meters in a straight line, turn around a designated marker, walk back to the chair, and sit down again. The time required to complete the test will be recorded in seconds.

Timepoint

Time points of assessment for dynamic balance: Baseline (before intervention) and at the end of the study (after intervention).

Method of measurement

Dynamic balance will be assessed using the Timed Up and Go (TUG) Test.

4

Description

Walking speed will be assessed using the 10-Meter Walk Test. In this test, participants will be instructed to walk a distance of 10 meters in the shortest possible time. Walking speed will be calculated by dividing the distance traveled (10 meters) by the time taken to complete the test and will be expressed in meters per second (m/s).

Timepoint

Time points of assessment for walking speed: Baseline (before intervention) and at the end of the study (after intervention).

Method of measurement

Walking speed will be assessed using the 10-Meter Walk Test.

5

Description

The range of motion (ROM) of the hip, knee, and ankle joints will be measured using a goniometer. The primary outcome will be the improvement of joint range of motion toward normal values.

Timepoint

Range of motion will be measured at baseline and at the end of the study.

Method of measurement

The range of motion (ROM) of the hip, knee, and ankle joints will be measured using a goniometer.

6

Description

Functional independence will be assessed using the Lawton and Brody IADL Scale. The maximum obtainable score is 8.

Timepoint

Functional independence will be assessed at baseline and at the end of the study.

Method of measurement

Functional independence will be assessed using the Lawton and Brody IADL Scale.

7

Description

Cognitive function will be assessed using the Mini-Mental State Examination (MMSE) and the Montreal Cognitive Assessment (MoCA). In the MoCA, a score of 26 or higher is considered normal, while in the MMSE, a score of 24 or higher is considered normal.

Timepoint

Cognitive function will be assessed at baseline and at the end of the study.

Method of measurement

Cognitive function will be assessed using the Mini-Mental State Examination (MMSE) and the Montreal Cognitive Assessment (MoCA).

8

Description

Quality of life will be assessed using the Older People's Quality of Life Questionnaire (OPQOL-35). Higher scores indicate better quality of life.

Timepoint

Quality of life will be measured at baseline and at the end of the study.

Method of measurement

Quality of life will be assessed using the Older People's Quality of Life Questionnaire (OPQOL-35).

9

Description

Fear of falling will be assessed using the Falls Efficacy

Scale–International (FES-I). A higher score indicates a greater fear of falling.

Timepoint

Fear of falling will be measured at baseline and at the end of the study.

Method of measurement

Fear of falling will be assessed using the Falls Efficacy Scale–International (FES-I).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Square-Stepping Exercise (SSE), three sessions per week, 60 minutes per session, for eight weeks.

Category

Rehabilitation

2

Description

Intervention Group 2: Otago Exercise Program (OEP), three sessions per week, 60 minutes per session, for eight weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadeghieh Nursing Home

Full name of responsible person

Mohammad Sadegh Katiraei

Street address

Sadeghieh Nursing Home, located at the end of Imam Khomeini Street, Industrial University Square, between Mahmoudabad Street and Aminabad Street, Isfahan, Iran.

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Isfahan

Full name of responsible person

Dr.Babak Saffari

Street address

First Floor, Central Library Building, University of Isfahan, University Street, Azadi Square, Isfahan, Iran.

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8174673441

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rokni@sci.ui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The University of Isfahan

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

The University of Isfahan

Full name of responsible person

Reyhane Jalali

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Sports Injuries and Corrective Exercise

Street address

No. 223, Aftab 3 Alley, Aftab Alley, Ordibehesht-e Sharghi Street, Baharestan, Isfahan, Iran

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Person responsible for updating data

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Full name of responsible person

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Latest degree

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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

Yes - There is 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

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

A subset of the data, such as information related to the primary outcome or similar variables, may be shared.

When the data will become available and for how long

6 months after publication of the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

De-identified data and study documents will not be made publicly available. In case of request, access to the data will only be granted with the approval of the principal investigator and in accordance with ethical guidelines and institutional regulations, while ensuring full confidentiality of participants.

From where data/document is obtainable

reyhanejalali7636@gmail.com

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

6 months after publication of the results

Comments