

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The Effects of Core Stability Exercises on Balance and Walking in Elderly Fallers with Mild Cognitive Impairment: A randomized control trial

Protocol summary

Study aim

evaluating the effects of Core Stability Exercises on Balance and Walking in Elderly Fallers with Mild Cognitive Impairment

Design

A randomized clinical trial study, single-blind, Factorial, 30 elderly randomized to intervention groups and a control group.

Settings and conduct

Participants are divided into two groups: core stability training, and control groups. This study was single-blind that the outcome assessor is blind to interventions. This study will be conducted in the neighbourhood of Tehran Municipality, District 7, and the participants will be explained the importance of protocol. The protocols are 8 weeks and three 40-minute sessions per week.

Participants/Inclusion and exclusion criteria

Had a history of falls in the last 6 month. Obtain score less than 24 on the Mini-mental state examination (MMSE). Able to walk without an Assistive Device.

Intervention groups

Intervention group: Core stability exercises - Exercises were performed for eight weeks and three sessions per week for the exercise group. The duration of each training session was 40 minutes, and each session included 5 minutes of warm-up and 5 minutes of cooling down. Core stability exercises consist of 3 levels. All exercises are under the supervision of a physiotherapist. In addition, the researcher stands close to the participant and is careful in all stages of training to prevent events such as falling. Exercises started from level 1, which included static contractions in a steady-state, level 2 exercises included static contractions in an unstable environment. Finally, level 3 exercises included dynamic movements in an unstable position. Control group: without any intervention. During this period, the control group asked to perform routine daily activities and not participate in specific exercises.

Main outcome variables

Static Balance, Dynamic Balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180627040251N3**

Registration date: **2020-08-19, 1399/05/29**

Registration timing: **retrospective**

Last update: **2020-08-19, 1399/05/29**

Update count: **0**

Registration date

2020-08-19, 1399/05/29

Registrant information

Name

Hassan Sadeghi

Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-10-27, 1398/08/05

Actual recruitment start date

2019-10-07, 1398/07/15

Actual recruitment end date

2019-12-06, 1398/09/15

Trial completion date

2020-02-29, 1398/12/10

Scientific title

The Effects of Core Stability Exercises on Balance and Walking in Elderly Fallers with Mild Cognitive Impairment: A randomized control trial

Public title

Effects of Core Stability Exercises on Balance and Walking in Elderly Fallers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Had a history of falls in the last 6 month Obtain score less than 24 on the Mini-mental state examination (MMSE) . Able to walk without an Assistive Device. 60 years of age and older with the ability and mobility to join the group training sessions.

Exclusion criteria:

Have acute or chronic disease with influence on balance control (e.g., Parkinson's disease; diabetes or peripheral neuropathy). Who participated in regular exercise programs in the last 6th month. Acute vision and hearing problems

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

After the initial evaluation, randomization was done using randomization blocks of 4 methods. Patients are randomly assigned to one of two groups through four random blocks. A member of the research team who is not involved in the selection of samples will determine the randomization sequence using an online randomization system (randomizer.org). Participants will be notified of their group allocation with a sealed envelope

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor is blind to the groups' randomization and interventions receiving by participants. in this way, during the evaluation before and after the intervention protocol, they do not make mistakes in their judgments in favour of a specific therapeutic intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Sport Sciences Research Institute (SSRI)

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No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran

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Postal code

1587958711

Approval date

2020-07-15, 1399/04/25

Ethics committee reference number

IR.SSRC.REC.1399.047

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

Fall

ICD-10 code

R29.6

ICD-10 code description

Repeated falls

2**Description of health condition studied**

Abnormalities of gait and mobility

ICD-10 code

R26

ICD-10 code description

Abnormalities of gait and mobility

3**Description of health condition studied**

Posture

ICD-10 code

R29.3

ICD-10 code description

Abnormal posture

4**Description of health condition studied**

Mild cognitive impairment

ICD-10 code

G31.84

ICD-10 code description

Mild cognitive impairment, so stated

5

Description of health condition studied

Strength Exercises

ICD-10 code

Y93.B9

ICD-10 code description

Activity, other involving muscle strengthening exercises

Primary outcomes

1

Description

Functional Mobility

Timepoint

Before the exercise program and after exercise program

Method of measurement

Timed Up and Go test (TUG)

Secondary outcomes

1

Description

Static Balance

Timepoint

Before the exercise program and after exercise program

Method of measurement

Single leg Stance test

2

Description

Walking

Timepoint

Before the exercise program and after exercise program

Method of measurement

10 Meter walking test

Intervention groups

1

Description

Intervention group: Core stability exercises - Exercises were performed for eight weeks and three sessions per week for the exercise group. The duration of each training session was 40 minutes, and each session included 5 minutes of warm-up and 5 minutes of cooling down. Core stability exercises consist of 3 levels. All exercises are under the supervision of a physiotherapist. In addition, the researcher stands close to the participant and is careful in all stages of training to prevent events such as falling. Exercises started from level 1, which included static contractions in a steady-state, level 2 exercises included static contractions in an unstable environment. Finally, level 3 exercises included dynamic movements in an unstable position. The exercises used

in this protocol, including the specific exercises to stabilize and the muscles of the spine, pelvic lumbar region, and abdomen.

Category

Rehabilitation

2

Description

Control group: without any intervention. During this period, the control group asked to perform routine daily activities and not participate in specific exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Department of Municipality District 7

Full name of responsible person

Miss Maryam Priyaie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi University

Full name of responsible person

Dr Ali Abbasi

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3th floor. Faculty of sport science and Physical Education, Shahid Keshvari Sports Complex, Razan Jonobi, Mirdamad,

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https://pess.khu.ac.ir/index.php?sid=42&slc_lang=en

Grant name

Grant code / Reference number

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

Title of funding source
Kharazmi University

Proportion provided by this source
70

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

Kharazmi University

Full name of responsible person

Dr Seyed sadradin Shojaedin

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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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