Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Oct 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)

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

City
Tehran

Province
Tehran

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
Street address
Gorgan Neighborhood House, Tavakoli Park, Shahid Madani St,
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info.region7@tehran.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kharazmi University
Full name of responsible person
Dr Ali Abbasi
Street address
3th floor. Faculty of sport science and Physical Education, Shahid Keshvari Sports Complex, Razan Jonobi, Mirdamad,
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33111-15447
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+98 21 2222 8001
Fax
Email
abbasi@khu.ac.ir

Web page address
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
Ḍr 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

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

Data Dictionary