

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of step exercise on risk factors related with fall in cognitively impaired older people

Protocol summary

Study aim

Determine the effect of step training on fall risk factors in the older adults with mild cognitive impairment

Design

The present research is a randomized, controlled, prospective clinical trial with parallel groups.

Settings and conduct

The present study will be carried out at the research center of Kermanshah University of Medical Sciences. Since the study nature, participants are not blind to the groups randomization, but statisticians and examiners are blind into groups randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria were included; aged over 65 years; Approval of Petersen's criteria to detect amnesic multiple-domain MCI and earning a score of 24 or more in Mini-Mental State Examination and less than 26 in the Montreal cognitive assessment. Exclusion criteria were included; Hospitalized older adults; History of depression, Anxiety or other mental disorders (ie, 5 <GDS-15); and receiving the drug for cognitive, neurological or musculoskeletal problems.

Intervention groups

A 24-week ST program, 3 times a week, and each session for 40 minutes, is performed on a black elastic mattress 2.5 meters long, 1 meter wide with 10 rows of squares, 25 cm x 25 centimeters. The ST program consists of a series of forward, backward, sideways and diagonal steps that, with each sequence, increases the complexity of the steppe combinations. The program sequence is organized according to six different difficulty levels: Junior, Basic, Regular, Regular, Senior and Master.

Main outcome variables

Balance; Frequency fall; balance static and dynamic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170114031942N11**

Registration date: **2018-09-27, 1397/07/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-27, 1397/07/05**

Update count: **0**

Registration date

2018-09-27, 1397/07/05

Registrant information

Name

Aynollah Naderi

Name of organization / entity

Shahrood University of Technology

Country

Iran (Islamic Republic of)

Phone

+98 917 721 7462

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of step exercise on risk factors related with fall in cognitively impaired older people

Public title

The effect of step exercise on risk factors related with fall in cognitively impaired older people

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

aged over 65 years Approval of Petersen's criteria (mild cognitive status test), to detect amnesic multiple-domain MCI earning a score of 24 or more in Mini-Mental State Examination and less than 26 in the Montreal Cognitive Assessment Have enough memory to remember the tips and understand the guidelines for participating in the study Independent Living in Society Walk without any help (for example, without the help of a cane or walker) Confirmation of the physician to participate in the study Sign the informed confirmation form of the participation in the research.

Exclusion criteria:

Institutional Elderly history of depression, anxiety or other mental disorders (ie, 5 <GDS-15) Receiving the drug for cognitive, neurological or musculoskeletal problems (such as a history of cardiovascular disease, Parkinson's disease, lower extremity surgery, significant orthopedic disorders or acute illness) Visual impairments in spite of glasses correction Acute or chronic conditions preventing participate in exercise Regular exercise ≥ 30 minutes per day and ≥ 3 days per week

Age

From **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **86**

Actual sample size reached: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate the participants in the research groups, a computerized list of random numbers for assigning random subjects to blocks (2, 4, 6,8) was identified by a statistical consultant using SPSS software. Then, the assignment of the participants is carried out by one of the research team members who are not associated with the 1: 1 assignment ratio within the training and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermansah University of Medical Sciences

Street address

Beheshti Blvd, Kermanshah, Kermanshah Province

City

Kermansah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-08-14, 1397/05/23

Ethics committee reference number

IR.KUMS.REC.1397.410

Health conditions studied

1

Description of health condition studied

mild cognitive impairment older people

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fall frequency

Timepoint

The frequency of falling during the study is measured monthly.

Method of measurement

Fall frequency test

Secondary outcomes

1

Description

Fear of falling

Timepoint

At the beginning of the study (before the intervention) and 12 and 24 weeks after the start of the step training

Method of measurement

Fall Efficacy Scale International

2

Description

Static Balance

Timepoint

At the beginning of the study (before the intervention) and 12 and 24 weeks after the start of the step training

Method of measurement

Frailty and Injuries: Cooperative Studies of Intervention Techniques-4

3

Description

Dynamic balance

Timepoint

At the beginning of the study (before the intervention) and 12 and 24 weeks after the start of the step training

Method of measurement

Dynamic Gait Index

4

Description

Reaction time

Timepoint

At the beginning of the study (before the intervention) and 12 and 24 weeks after the start of the step training

Method of measurement

Switch Mat

5

Description

Falling index

Timepoint

At the beginning of the study (before the intervention) and 12 and 24 weeks after the start of the step training

Method of measurement

Physiological Profile Assessment

6

Description

Executive Performance

Timepoint

At the beginning of the study (before the intervention) and 12 and 24 weeks after the start of the step training

Method of measurement

Stroop Color-Word, A-B part of Trail-Making Test, Digit Symbol Substitution Test

Intervention groups

1

Description

Intervention group: The participants of this group will participate in a 24-week training program, which will be conducted through three 40 minute sessions per week. Step training is performed on the black and white elastic mat with 2.5 meters long, 1 meter wide and 10 rows of squares, 25 cm x 25 centimeters. The ST program consists of a series of forward, backward, sideways and diagonal steps that, with each sequence, increases the complexity of the step training. The program sequence is organized according to six different levels of difficulty: Junior, Basic, Semi Regular, Regular, Senior and Master.

Category

Prevention

2

Description

Control group: Control group participants continue their day-to-day activities and do not receive any special intervention

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah Senior Care Center

Full name of responsible person

Ali Hosseni

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Technology

Full name of responsible person

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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

Shahroud University of Technology

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
Shahrood University of Technology
Full name of responsible person
Aynollah Naderi
Position
Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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