Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

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

Public title
The effect of step excersice 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 amnestic 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
Street address
Taghvestan blvd
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6761753164
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Technology
Full name of responsible person
Aynollah Naderi
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Tehran avenue
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3619995161
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ay.naderi@yahoo.com
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

Latest degree

Ph.D.

Other areas of specialty/work

Physical Education and Sports Science

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Person responsible for scientific inquiries

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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