

# 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

##### Email address

ay.naderi@shahroodut.ac.ir

#### 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  $\geq 30$  minutes per day and  $\geq 3$  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

#### City

Kermansah

#### Province

Kermanshah

#### Postal code

6761753164

#### Phone

+98 83 4522 6103

#### Email

asakenapoor@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shahroud University of Technology

#### Full name of responsible person

Aynollah Naderi

#### Street address

Tehran avenue

#### City

Shahroud

#### Province

Semnan

#### Postal code

3619995161

#### Phone

+98 23 3239 2204

#### Email

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  
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Assistant Professor  
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## Person responsible for scientific inquiries

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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