

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Study of the effect of task - oriented training with altered sensory input on balance in the elderly people

#### Protocol summary

##### Study aim

the Effect of task - oriented training with altered sensory input in balance of elderly persons

##### Design

A randomized, blind clinical trial will be conducted with the parallel group plan of 10 elderly people .The study groups consisted of a treatment group and a control group. All tests are performed by one person and testers also patients are blinded to the study groups.

##### Settings and conduct

The site of this study will be the Neuro-Muscular Rehabilitation Center. According to a sample study, these interventions are performed 3 times a week for 4 weeks, and each session lasts about 1 hour. People receive balance tests and functional mobility 1 week before and 1 week after exercise. All tests are performed by one person and testers and patients are blinded to the study groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having at least 60 years of old Ability to walk independently and without auxiliary equipment at least 10 meters in length Having a cognitive performance level above 21 in the MMSE test Having at least 1 falling in the last 6 months Not having any neurological or other disease Exclusion criteria: Disconnecting the person in the intervention sessions Absence of referrals for second-stage tests Not able to complete activities and progress to its harder levels

##### Intervention groups

Treatment group: A group that uses the protocol designed for equilibrium exercises. These exercises consist of 12 sessions, which are based on two principles of internalization of the body's sense of emotion and individual safety. These treatments sit in 4 positions, sitting, sit to stand, standing and walking. Each of these four positions is performed for 10 minutes and is restrained between each state for 30 seconds. Before and after the exercises, warm-up and cool-down exercises each take 5 minutes of muscle stretching.

Control group: A group that only receives current rehabilitation exercises.

##### Main outcome variables

Balance and functional mobility that will be measured using the Berg Balance Scale and Time Up and Go tests

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180217038762N1**

Registration date: **2018-03-12, 1396/12/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-12, 1396/12/21**

Update count: **0**

##### Registration date

2018-03-12, 1396/12/21

##### Registrant information

##### Name

Fatemeh Daneshjoo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3332 8502

##### Email address

FatemehDaneshjoo@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-24, 1396/12/05

##### Expected recruitment end date

2018-05-21, 1397/02/31

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Study of the effect of task – oriented training with altered sensory input on balance in the elderly people

**Public title**  
:The effect of task - oriented training in elderly"

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having at least 60 years of old Ability to walk independently and without auxiliary equipment at least 10 meters in length Having a cognitive performance level above 21 in the MMSE test Having at least 1 incidence in the last 6 months Not having any neurological or other disease  
**Exclusion criteria:**  
Disconnecting the person in the examinations and intervention sessions Absence of referrals for second-stage tests Not able to complete activities and progress to its harder levels

**Age**  
From 60 years old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: 10

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Random numbers

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, participants and evaluator will be unaware of how people are categorized into intervention and control groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Semnan University of Medical Science  
**Street address**  
Ghods blvd, Neuromuscular Research Center  
**City**  
Semnan  
**Province**  
Semnan  
**Postal code**  
35196\_98375  
**Approval date**  
2018-02-05, 1396/11/16  
**Ethics committee reference number**  
IR.SEMUMS.REC.1396.216

## Health conditions studied

1

**Description of health condition studied**  
Elderly people  
**ICD-10 code**  
**ICD-10 code description**

## Primary outcomes

1

**Description**  
Balance score in the Berg Balance Scale  
**Timepoint**  
1 week before and one week after intervention  
**Method of measurement**  
Berg Balance Scale

2

**Description**  
Functional mobility score in Time Up and Go test  
**Timepoint**  
1 week before and one week after intervention  
**Method of measurement**  
Time Up and Go test

## Secondary outcomes

empty

## Intervention groups

1

**Description**  
Intervention group: The Equilibrium Exercise Program consists of 12 sessions of practice, which is based on three principles of inputs of the somatosensory, the difficulty of tasks and individual safety. Each of these four states is performed for 10 minutes and is restrained

between each state for 30 seconds.

**Category**

Rehabilitation

**2**

**Description**

Control group: This group uses only common rehabilitation exercises

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Nueromuscular rehabilitation research center

**Full name of responsible person**

Fatemeh Daneshjoo

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Nueromuscular rehabilitation research center ,Ghods blvd, Semnan

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Mohammadreza Asgari

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Semnan University of Medical Science, Basij blvd, Semnan

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**Email**

asgari5000@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Semnan University of Medical Sciences

**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**

Semnan University of Medical Sciences

**Full name of responsible person**

Fatemeh Daneshjoo

**Position**

lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Occupational Therapy

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**Contact**

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**Position**

lecturer

**Latest degree**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
Fatemeh Daneshjoo  
**Position**  
lecturer  
**Latest degree**  
Master  
**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

### Title and more details about the data/document

Reproductive in the field of rehabilitation and behavioral science

### When the data will become available and for how long

1 years

### To whom data/document is available

researchers

### Under which criteria data/document could be used

Reproductive in the field of rehabilitation and behavioral science

### From where data/document is obtainable

Semnan University of Medical Science

### What processes are involved for a request to access data/document

Supervision of the Student Research Committee of Semnan University of Medical Science - Fulfillment of main investigator obligation

### Comments