

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study of the effect of task-oriented exercise with altered sensory input on Activity of Daily Living in the elderly people

#### Protocol summary

##### Study aim

Determination of the effect of task-oriented exercise with altered sensory input on the ability to control urine and feces, feeding, mobility, dressing, climbing stairs and bathing in elderly people.

##### 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 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 group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having at least 60 years of old and ability to walk independently Exclusion criteria: Having neurological or orthopedic disease

##### 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

Activity of Daily Living that will be measured using the

Barthel index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180217038762N2**

Registration date: **2019-01-02, 1397/10/12**

Registration timing: **prospective**

Last update: **2019-01-02, 1397/10/12**

Update count: **0**

##### Registration date

2019-01-02, 1397/10/12

##### 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

2019-01-21, 1397/11/01

##### Expected recruitment end date

2019-03-19, 1397/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Study of the effect of task-oriented exercise with altered sensory input on Activity of Daily Living in the elderly people

### Public title

The effect of task-oriented exercise in elderly people

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Having at least 60 years of old Ability to walk independently and without auxiliary equipment Not having any neurological or other disease Having a cognitive performance level at least 21 in the MMSE test

#### Exclusion criteria:

Non-cooperation and referral of the individual in the tests Inability to complete activities

### Age

From **60 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant

### Sample size

Target sample size: **10**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple randomization through random numbers

### Blinding (investigator's opinion)

Single blinded

### Blinding description

In this study, participants will be unaware of how people are categorized in to 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 of Semnan University of Medical Science

##### City

Semnan

### Province

Semnan

### Postal code

98375-35196

### Approval date

2018-12-18, 1397/09/27

### Ethics committee reference number

IR.SEMUMS.REC.1397.209

## Health conditions studied

### 1

#### Description of health condition studied

elderly

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

ADL score in Barthel index

#### Timepoint

1 week before and 1 week after intervention

#### Method of measurement

Barthel index

## 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 exercise

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Neuromuscular rehabilitation research center  
**Full name of responsible person**  
Fateme Daneshjoo  
**Street address**  
Neuromuscular rehabilitation research center  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
دکتر پرویز کوخایی  
**Street address**  
Semnan University of Medical Science, Basij blvd,  
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3514799442  
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**Email**  
p\_kokha@yahoo.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

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Fateme Daneshjoo  
**Position**  
lecturer  
**Latest degree**  
Master  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**

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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

**Data Dictionary**

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