# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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, siting, 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**
Fatemeh 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, Semnan

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**Phone**
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**Email**
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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**
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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## Person responsible for updating data

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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