

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

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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

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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Phone
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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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lecturer
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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