

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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

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Semnan University of Medical Science, Basij blvd,
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3514799442

Phone

+98 23 3345 1336

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

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