Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 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)

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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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3514799442

Phone
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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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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