

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of the effect of task - oriented training with altered sensory input on balance in the elderly people

Protocol summary

Study aim

the Effect of task - oriented training with altered sensory input in balance of elderly persons

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 testers also 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 groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having at least 60 years of old Ability to walk independently and without auxiliary equipment at least 10 meters in length Having a cognitive performance level above 21 in the MMSE test Having at least 1 falling in the last 6 months Not having any neurological or other disease Exclusion criteria: Disconnecting the person in the intervention sessions Absence of referrals for second-stage tests Not able to complete activities and progress to its harder levels

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

Balance and functional mobility that will be measured using the Berg Balance Scale and Time Up and Go tests

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180217038762N1**

Registration date: **2018-03-12, 1396/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-12, 1396/12/21**

Update count: **0**

Registration date

2018-03-12, 1396/12/21

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

2018-02-24, 1396/12/05

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of task - oriented training with altered sensory input on balance in the elderly people

Public title
:The effect of task - oriented training in elderly"

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having at least 60 years of old Ability to walk independently and without auxiliary equipment at least 10 meters in length Having a cognitive performance level above 21 in the MMSE test Having at least 1 incidence in the last 6 months Not having any neurological or other disease
Exclusion criteria:
Disconnecting the person in the examinations and intervention sessions Absence of referrals for second-stage tests Not able to complete activities and progress to its harder levels

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
Random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants and evaluator will be unaware of how people are categorized into 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
City
Semnan
Province
Semnan
Postal code
35196_98375
Approval date
2018-02-05, 1396/11/16
Ethics committee reference number
IR.SEMUMS.REC.1396.216

Health conditions studied

1

Description of health condition studied
Elderly people
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Balance score in the Berg Balance Scale
Timepoint
1 week before and one week after intervention
Method of measurement
Berg Balance Scale

2

Description
Functional mobility score in Time Up and Go test
Timepoint
1 week before and one week after intervention
Method of measurement
Time Up and Go test

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 exercises

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Nueromuscular rehabilitation research center

Full name of responsible person

Fatemeh Daneshjoo

Street address

Nueromuscular rehabilitation research center ,Ghods blvd, Semnan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammadreza Asgari

Street address

Semnan University of Medical Science, Basij blvd, Semnan

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3514799442

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Email

asgari5000@gmail.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 scientific inquiries

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

Semnan University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

Reproductive in the field of rehabilitation and behavioral science

When the data will become available and for how long

1 years

To whom data/document is available

researchers

Under which criteria data/document could be used

Reproductive in the field of rehabilitation and behavioral science

From where data/document is obtainable

Semnan University of Medical Science

What processes are involved for a request to access data/document

Supervision of the Student Research Committee of Semnan University of Medical Science - Fulfillment of main investigator obligation

Comments