Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, 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
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

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3514799442

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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 updating data

Contact
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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