Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A randomized controlled trial to investigate the effect of sensory reweighting as a method of balance exercises on postural control, functional balance and mobility, activities of daily living, anxiety and stress suffering from chronic stroke

Protocol summary

Summary

The aim of this study is to investigate the effect of sensory reweighting as a method of balance exercises on postural control, functional balance and mobility, activities of daily living, anxiety and stress in patients with chronic stroke. In this clinical trial study, 40 patients with chronic stroke will be randomly assigned to two groups: a group receiving sensory reweighting as a method of balance exercises and control group. Randomization will be performed by the person who is not involved in the study using sequentially numberd sealed envelopes. The main inclusion criteria include having the first experience of stroke, the ability to perform the most difficult condition of laboratory test (quiet standing for 180 seconds while vibration is applied on the Achilles tendons of both sides and attention to visual stimulus) and an acceptable level of cognitive function, i.e. score equal to or greater than 23 on the Mini Mental State Examination test. In the case of co-morbid other neurological diseases, orthopedic disorders (such as low back pain, arthritis, hallux valgus, flat foot), diabetes or addiction, subjects will be excluded. Intervention group will receive 24 sessions of sensory reweighting as a method of balance exercises (8 weeks, 3 sessions per week, 45-60 minutes per session). Control group will receive conventional rehabilitation. Primary outcome measures (postural control, functional balance and mobility, activities of daily living, anxiety and stress) and secondary outcome measures (participation, instrumental activities of daily living, sleep quality, fatigue, quality of life, fear of fall, pain, depression and functional balance) will be evaluated before and after receiving sensory reweighting exercises and 8 weeks after receiving these exercises in the intervention group and before and after conventional rehabilitation and 8 weeks after conventional rehabilitation in the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071916830N7**
Registration date: **2017-11-09, 1396/08/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-09, 1396/08/18

Registrant information

Name

Ghorban Taghizadeh

Name of organization / entity

School of Rehabilitation Sciences, Iran University of Medical

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7124

Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized controlled trial to investigate the effect of sensory reweighting as a method of balance exercises on postural control, functional balance and mobility, activities of daily living, anxiety and stress suffering from chronic stroke

Public title
The effect of rehabilitation exercises on balance in patients with chronic stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Having the first experience of stroke; Ability to walk 10 meters without assistive devices; Having an acceptable level of cognitive function, i.e. score equal to or greater than 23 on the Mini Mental State Examination; Having at least fifth grade education; Having the ability to perform the most difficult condition of laboratory test (quiet standing for 180 seconds while vibration is applied on the Achilles tendons of both sides and attention to visual stimulus); Ability to read a sentence from the screen at a distance of 2 meters. Exclusion criteria: Co-morbid other neurological diseases, orthopedic disorders (such as low back pain, arthritis, hallux valgus, flat foot), diabetes or addiction according to the report of patient, or the patient's family or physician; History of falling during the past month according to the report of patient, or the patient's family.
Age
From **25 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization will be performed by the person who is not involved in the study using sequentially numberd sealed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
City
Tehran
Postal code
1449614535
Approval date
2016-07-11, 1395/04/21
Ethics committee reference number
IR.IUMS.REC 1396.31212

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
I64
ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
Postural control
Timepoint
Before and after intervention and 8 weeks after intervention
Method of measurement
Force plate (postural sway parameters)

2

Description
Functional balance and mobility
Timepoint
Before and after intervention and 8 weeks after intervention
Method of measurement
Fuctional reach test, Berg Balance Scale Questionnaire, Timed Up & Go Test, Tinetti Balance test, Six Minute Walk Test, Activities-Specific Balance Confidence Scale Questionnaire, Dynamic gait index Questionnaire, gait speed

3

Description
Anxiety
Timepoint
Before and after intervention and 8 weeks after intervention
Method of measurement
Beck Anxiety Questionnaire, Hamilton Anxiety Scale Questionnaire, Depression, Anxiety, Stress Scales (DASS) Questionnaire

4

Description
Activities of daily living
Timepoint
Before and after intervention and 8 weeks after intervention
Method of measurement
Barthel Index Questionnaire

5

Description
Stress
Timepoint
Before and after intervention and 8 weeks after intervention
Method of measurement
Depression, Anxiety, Stress Scales (DASS) Questionnaire

Secondary outcomes

1

Description
Participation
Timepoint
Before and after intervention and and 8 weeks after intervention
Method of measurement
Canadian occupational performance measure Questionnaire

2

Description
Instrumental activities of daily living
Timepoint
Before and after intervention and 8 weeks after intervention
Method of measurement
Lawton Instrumental activities of daily living Scale Questionnaire

3

Description
Sleep quality
Timepoint
Before and after intervantion and 8 weeks after intervention
Method of measurement
Pittsburgh Sleep Quality Index Questionnaire

4

Description
Fatigue
Timepoint
Before and after intervantion and 8 weeks after intervention
Method of measurement
Fatigue severity scale Questionnaire, Visual analog scale of fatigue

5

Description
Quality of life
Timepoint
Before and after intervantion and 8 weeks after intervention
Method of measurement
World health organization quality of life assessment Questionnaire

6

Description
Fear of fall
Timepoint
Before and after intervantion and 8 weeks after intervention
Method of measurement
Fall efficacy scale Questionnaire

7

Description
Pain
Timepoint
Before and after intervantion and 8 weeks after intervention
Method of measurement
Brief pain inventory Questionnaire, Short-Form McGill Pain Questionnaire, Visual analog scale of pain

8

Description
Depression
Timepoint
Before and after intervantion and 8 weeks after intervention
Method of measurement
Depression Anxiety Stress Scales (DASS) Questionnaire, Visual analog scale of depression

9

Description
Functional balance
Timepoint
Before and after intervantion and 8 weeks after

intervention

Method of measurement

Duration of standing on each leg with open and closed eyes, Duration of tandem standing with open and closed eyes

Intervention groups

1

Description

Control group: receives conventional rehabilitation.

Category

Rehabilitation

2

Description

Intervention group: In addition to conventional rehabilitation, receives 24 sessions of sensory reweighting as a method of balance exercises (8 weeks, 3 sessions per week, 45-60 minutes per session). Exercises include proprioceptive, visual, vestibular, combination of proprioceptive and vestibular, combination of visual and vestibular and combination of proprioceptive and visual stimulations.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation centers and hospitals in Tehran

Full name of responsible person

Ghorban Taghizadeh

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Malakouti

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ghorban Taghizadeh

Position

PhD in Neurosciences/ Assistant Professor

Other areas of specialty/work

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Full name of responsible person

Ghorban Taghizadeh

Position

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Web page address

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Ghorban Taghizadeh

Position
PhD in Neuroscience/ Assistant Professor

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty