

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 numbered 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 numbered 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 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 intervention and 8 weeks after intervention

Method of measurement

Pittsburgh Sleep Quality Index Questionnaire

4

Description

Fatigue

Timepoint

Before and after intervention 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 intervention 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 intervention and 8 weeks after intervention

Method of measurement

Fall efficacy scale Questionnaire

7

Description

Pain

Timepoint

Before and after intervention 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 intervention 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 intervention 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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Ghorban Taghizadeh

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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