

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Sep 2026

The effect of extroceptive and proprioceptive sensory stimulation on Activities of Daily Living, motor function and spasticity of upper limb in stroke patients

Protocol summary

Summary

Objectives: The aim of this study is to evaluate the effect of extroceptive and proprioceptive sensory stimulation on ADL, motor function and spasticity of upper limb in stroke patients. Design: Participants are from chronic stroke patients 50 years of age who are referred to the rehabilitation clinic in Isfahan Red Crescent. 60 eligible participants, are randomly assigned into control and intervention groups by coded envelopes. Setting and conduct: Evaluations are done three times before and after the intervention, and three weeks after intervention by a trained Occupational Therapist who is blind to type of group. Participants: Participants must have experienced just one stroke and live in chronic period. Interventions: After the initial evaluation sessions, sessions for intervention group is occupational therapy in addition to traditional interventions, including 4 sessions per week for 6 weeks and each session 45 minutes. Each session of intervention includes: Extroceptive and proprioceptive sensory stimulation. The control group receives occupational therapy traditional interventions. The main outcome measures: Barthel-index assessment test to assess activities of daily living, Fugle-meyer test to evaluate hand motor function, and Modified Ashworth scale used to evaluate spasticity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610223551N4**
Registration date: **2016-11-12, 1395/08/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-12, 1395/08/22

Registrant information

Name

Parvin Raji

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for education, Tehran University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of extroceptive and proprioceptive sensory stimulation on Activities of Daily Living, motor function and spasticity of upper limb in stroke patients

Public title

The effect of extroceptive and proprioceptive sensory stimulation on Activities of Daily Living, motor function and spasticity of upper limb in stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Only have experienced one stroke; live in chronic phase (more than 6 months have passed since their stroke); able to detect monofilament number 4.31 in their fingers; according to the Brunnstrom assessment criteria are in step 4 or upper than; have the ability to understand commands that have a point. Exclusion criteria: During the study, patients who experienced recurrent stroke or have no appropriate cooperation with the therapist or are absent in their therapy sessions are excluded.

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization was performed using sealed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poursina St, Ghods St, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2016-10-17, 1395/07/26

Ethics committee reference number

IR.TUMS.VCR.REC.1395.789

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

G45

ICD-10 code description

G45

Primary outcomes

1

Description

Activities of daily living

Timepoint

before intervention, three weeks after intervention, after intervention

Method of measurement

Barthel Index

Secondary outcomes

1

Description

Spasticity

Timepoint

before intervention, three weeks after intervention, after intervention

Method of measurement

Modified Ashworth scale

2

Description

hand function

Timepoint

before intervention, three weeks after intervention, after intervention

Method of measurement

Fugle-meyer test

Intervention groups

1

Description

Exteroceptive sensory stimulation such as brushing, icing, stretch pressure and Proprioceptive stimulation such as weight bearing on upper limb joints, including 4 sessions per week for 6 weeks and each session 45 minutes.

Category

Rehabilitation

2

Description

Traditional occupational therapy interventions

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation clinic in Isfahan Red Crescent

Full name of responsible person

Maryam Derakhshanfar

Street address

Rehabilitation clinic in Isfahan Red Crescent

City

Isfahan

Sciences, Picheshemiran, Enghelab Ave, Tehran,Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Parvin Raji

Position

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for education,Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Jalili

Street address

Vice chancellor for education,7th floor,Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran

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 education,Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Parvin Raji

Position

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Other areas of specialty/work

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Rehabilitation faculty of Tehran University of Medical

Person responsible for updating data

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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*