

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7753 8798

###### Email address

praji@tums.ac.ir

##### 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

## 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**

lecturer

**Other areas of specialty/work**

**Street address**

Rehabilitation faculty of Tehran University of Medical

Sciences, Picheshemiran, Enghelab Ave, Tehran, Iran

**City**

Tehran

**Postal code**

**Phone**

+98 21 7753 3939

**Fax**

**Email**

praji@tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Parvin Raji

**Position**

lecturer

**Other areas of specialty/work**

**Street address**

Rehabilitation faculty of Tehran University of Medical Sciences, Picheshemiran, Enghelab Ave, Tehran, Iran

**City**

Tehran

**Postal code**

**Phone**

+98 21 7753 3939

**Fax**

**Email**

praji@tums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Parvin Raji

**Position**

lecturer

**Other areas of specialty/work**

**Street address**

Rehabilitation faculty of Tehran University of Medical Sciences, Picheshemiran, Enghelab Ave, Tehran, Iran

**City**

Tehran

**Postal code**

**Phone**

+98 21 7753 3939

**Fax**

**Email**

praji@tums.ac.ir

**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*