

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparison of the effectiveness of cognitive rehabilitation of stroke patients with spatial neglect using the Prism Adaption and combined Prism Adaption and the Trans-cranial Magnetic Stimulation: a randomized control clinical trial

#### Protocol summary

##### Study aim

This study aimed to investigate the effect of cognitive rehabilitation using the prism combined the trans cranial magnetic stimulation among stroke patients with spatial neglect

##### Design

This study will be a single blind, sham controlled randomize clinical trial in phase 2 with parallel group design. There will be 18 patient with stroke related neglect that will enroll between August 2017 and September 2018.

##### Settings and conduct

The Intervention group: The stroke patients with neglect underwent Continuous theta-burst Trans cranial Magnetic Stimulation combined with Prism Adaptation to mirror therapy for 10 sessions. The control group: The stroke patients with neglect underwent sham Trans cranial Magnetic Stimulation combined with prism adaptation to mirror therapy for 10 sessions. Neglect and stroke-related functional assessment tests will be administered before and after 10 sessions of therapy for assessment of therapy efficacy. The present study will be conducted at Shariati Hospital and the National Center for Mapping of the Brain;

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Neglect due to stroke; being right handed. Non inclusion criteria: age less than 18 and more than 80 years; severe head trauma in the last 3 months; severe chronic health conditions such as advanced cancer; dementia; heart pacemaker.

##### Intervention groups

The intervention group will receive Continuous theta-burst Trans cranial Magnetic Stimulation combined with Prism Adaptation to mirror therapy for 10 sessions. The stroke patients in the sham group will receive sham Trans cranial Magnetic Stimulation combined with prism

adaptation to mirror therapy for 10 sessions.

##### Main outcome variables

Unilateral neglect

#### General information

##### Reason for update

##### Acronym

cognitive rehabilitation Trans-cranial Magnetic Stimulation (TMS) Prism Adaption (PA)

##### IRCT registration information

IRCT registration number: **IRCT20170423033606N3**

Registration date: **2018-11-25, 1397/09/04**

Registration timing: **retrospective**

Last update: **2018-11-25, 1397/09/04**

Update count: **0**

##### Registration date

2018-11-25, 1397/09/04

##### Registrant information

##### Name

SHole Vatanparasti

##### Name of organization / entity

ICSS

##### Country

Iran (Islamic Republic of)

##### Phone

+98 433839881

##### Email address

sholevatanparast100@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

**Expected recruitment start date**

2017-07-22, 1396/04/31

**Expected recruitment end date**

2018-11-21, 1397/08/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of cognitive rehabilitation of stroke patients with spatial neglect using the Prism Adaption and combined Prism Adaption and the Trans-cranial Magnetic Stimulation: a randomized control clinical trial

**Public title**

The effect of Prism Adaption and the Trans-cranial Magnetic Stimulation in spatial neglect treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The right-handed patients stroke in right hemisphere with unilateral neglect

**Exclusion criteria:**

Minimum age 18 and Maximum age 80 years intense pain cerebral edema brain trauma pacemaker of heart National Institutes of Health Stroke scale

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **18**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants will be assigned to one of two groups with the help of random numbers table.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

After randomization, intervention group patients will receive trans cranial magnetic stimulation (TMS) with the following protocol: 801 pulses will be delivered in 267 bursts and each burst consisted of 3 pulses at 30 Hz. Each session of stimulation will last 45 seconds as stimulation bursts will be delivered at 6 Hz. Magnetic coil will be tangentially placed at P3, with the handle pointing posterior. Sham group patients will receive the same stimulation protocol and the magnetic coil will be placed at P3. The only difference will be holding the magnetic coil vertical to the scalp that will resulted in no brain stimulation during the stimulation period. However,

patients will hear magnetic pulses' sounds (clicks) without receiving any stimulation.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Between Sheikh Fazlollah Noori and Shahid Chamran highway, Shahid Hemmat high way

**City**

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**Postal code**

57168-47146

**Approval date**

2017-05-13, 1396/02/23

**Ethics committee reference number**

IR.IUMS.REC.1396.93012334

**Health conditions studied****1****Description of health condition studied**

Stroke with unilateral spatial neglect

**ICD-10 code**

I64

**ICD-10 code description**

Stroke, not specified as hemorrhage or infarction

**Primary outcomes****1****Description**

Unilateral neglect

**Timepoint**

Before and after 10 session treatment

**Method of measurement**

Line Bisection Test; Star Cancellation Test; The Catherine Bergego Scale

**Secondary outcomes**

## 1

### **Description**

Neurological function

### **Timepoint**

Before and after 10 session treatment

### **Method of measurement**

The Modified Rankin Scale and The Barthel Index Scale

## 2

### **Description**

Writing errors of unilateral neglect

### **Timepoint**

Before and after 10 session treatment

### **Method of measurement**

The Writing Test

## 3

### **Description**

Painting of unilateral neglect

### **Timepoint**

Before and after 10 session treatment

### **Method of measurement**

The Painting Coloring Test

## 4

### **Description**

Reading of unilateral neglect

### **Timepoint**

Before and after 10 session treatment

### **Method of measurement**

The Reading Test

## 5

### **Description**

Copying shape of unilateral neglect

### **Timepoint**

Before and after 10 session treatment

### **Method of measurement**

The O'clock Test and The Copying Shape

## 6

### **Description**

Aphasia of unilateral neglect;;

### **Timepoint**

Before and after 10 session treatment;;

### **Method of measurement**

Persian Diagnostic Aphasia Battery-Aphasia Quotient Test,Persian Picture Naming Battery Test, Picture Naming

## 7

### **Description**

Memory of unilateral neglect

### **Timepoint**

Before and after 10 session treatment

### **Method of measurement**

Wechsler Memory Scale: Sub Test, River Mill Scale: Sub Test, Rey Auditory Verbal Learning Test

## 8

### **Description**

Spatial ability unilateral neglect

### **Timepoint**

Before and after 10 session treatment

### **Method of measurement**

Mental Rotation Test,Visualizing Test and Water Level Test

## **Intervention groups**

### 1

#### **Description**

Intervention group: In each session, patients will receive trans cranial magnetic stimulation (TMS). Inhibitory TMS will be as following protocol: 801 pulses will be delivered in 267 bursts and each burst will consist of 3 pulses at 30 Hz. Each session of stimulation will last 45 seconds as stimulation bursts will deliver at 6 Hz. Magnetic coil will place tangentially at P3 and the coil handle will be placed in posterior. After stimulation, patients will receive mirror therapy for 20 minutes while will wear prism glasses. Prism adaption glasses will deviate the visual fields 10 degrees to the right. In each 20 minutes of mirror therapy, patients will sit at a table containing a vertical mirror with the size of 35\*35\*30 cm. Patients will be asked to put their pare tic hands inside the mirror box and their intact hand in front, so mirror image of the intact hand will seem as the pare tic hand in the patients' eyes. Then, patients will open and close their hands and fingers while will look at their hands' images in the mirror. Also, they will try to do the same movements with their pare tic hands meanwhile. This therapy will continue for 10 daily sessions in 2 weeks.

#### **Category**

Rehabilitation

### 2

#### **Description**

Sham stimulation control group: In each session, patients will receive trans cranial magnetic stimulation (TMS). Inhibitory TMS will be as following protocol: 801 pulses will deliver in 267 bursts and each burst will consist of 3 pulses at 30 Hz. Each session of stimulation will last 45 seconds as stimulation bursts will deliver at 6 Hz. Magnetic coil will couple vertically place at P3, with the handle will be placed at posterior. After stimulation, patients will receive mirror therapy for 20 minutes while will wear prism glasses. Prism adaption glasses will deviate the visual fields 10 degrees to the right. In each 20 minutes of mirror therapy, patients will sit at a table contain a vertical mirror in size of 35\*35\*30 cm. Patients will ask to put their pare tic hands inside the mirror box and their intact hand in front, so mirror image of the intact hand will seem as the pare tic hand to the patients' eyes. Then, patients will open and close their hands and fingers while will look at their hands' images in the mirror. Also, they will try to do the same movements with their pare tic hands meanwhile. This therapy will be done during 10 daily sessions for 2

weeks.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shariati hospitalal

**Full name of responsible person**

Shahram Ovis Garan

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Next to University Tarbiyat Modares.,Kargar Jonobi Street.

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Cognitive Sciences & Technologies Council

**Full name of responsible person**

Najib Nili

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[http://cogc.ir/index.php?ctrl=static\\_page&lang=1&id=1021](http://cogc.ir/index.php?ctrl=static_page&lang=1&id=1021)

**Grant name**

Encouragement Support by the Department of Cognitive Science Development Support for Ph.D.;

**Grant code / Reference number**

4975

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

Yes

**Title of funding source**

Cognitive Sciences & Technologies Council

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

SHole Vatanparasti

**Position**

PHD student in cognitive psychology

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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Master

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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences  
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**Latest degree**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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