Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Augusta 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)

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+98 433839881

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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
Tehran
Province
Tehran
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
Ṡhahram 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

Street address
No. 35 ,Barmak alley, Arjantin Square

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research@cogc.ir

Web page address
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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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