

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of the order of Transcranial direct current stimulation and Computer-based Cognitive Rehabilitation on Improving Cognitive Performance and Activities of Daily Living Patient with Stroke

#### Protocol summary

##### Study aim

Comparison of the effect of the order of Transcranial direct current stimulation and Computer-based Cognitive Rehabilitation on Improving Cognitive Performance and Activities of Daily Living of People with Stroke

##### Design

Clinical trial with control group, double blind, randomized, with four groups.

##### Settings and conduct

Sampling will be conducted from Iran University of Medical Sciences hospitals. Interventions will be done in the brain and cognition clinic of the cognitive neuroscience research institute.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : diagnosis of ischemic stroke of anterior and medial cerebral arteries or one of the arteries by the neurologist and MRI, No aphasia and associated neurological disorders (Parkinson's, MS, ALS, Alzheimer's), only one stroke ,Post stroke time (1-12 months), Age 20 - 75 years, educated (9 successful grades) . Exclusion criteria: failure to participate in two consecutive treatment sessions, change in medication during the course of the intervention, headache.

##### Intervention groups

.Interventions include ten sessions each twenty-minute tDCS on c3 or c4 and 30 to 40 minute Captain's log computer based rehabilitation training programs. Therapeutic groups include four groups:Group 1: First tDCS session and then computer based cognitive rehabilitation. Group 2: First, computer based cognitive rehabilitation and then tDCS. Third group: Simultaneously computer based cognitive rehabilitation and tDCS. Group 4:Simultaneously sham tDCS and computer based cognitive rehabilitation.

##### Main outcome variables

1-Improving executive functions 2-promoting independence in basic and instrumental daily life

activities.

#### General information

##### Reason for update

##### Acronym

TDCs

##### IRCT registration information

IRCT registration number: **IRCT20120910010806N8**

Registration date: **2019-06-15, 1398/03/25**

Registration timing: **retrospective**

Last update: **2019-06-15, 1398/03/25**

Update count: **0**

##### Registration date

2019-06-15, 1398/03/25

##### Registrant information

##### Name

Malahat Akbarfahimi

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 7124

##### Email address

akbarfahimi.m@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-07-23, 1396/05/01

##### Expected recruitment end date

2018-07-23, 1397/05/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of the order of Transcranial direct current stimulation and Computer-based Cognitive Rehabilitation on Improving Cognitive Performance and Activities of Daily Living Patient with Stroke

**Public title**

the effect of the order of Transcranial direct current stimulation and Computer-based Cognitive Rehabilitation on Improving Cognitive Performance and Activities of Daily Living

**Purpose**

Treatment

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

schemic stroke in the anterior and medial cerebral arteries or one of the arteries. Neurologist by MRI No aphasia and associated neurological disorders (Parkinson's, MS, ALS, Alzheimer's disease) First stroke of the patient and one to twelve months after the stroke Admission Age Between 20 and 75 Years At least 9 successful grades literacy

**Exclusion criteria:**

Not attending two consecutive treatment sessions Change the medication during the course of the intervention Create headaches

**Age**

From **20 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

By convenient method the records of inpatients and outpatients stroke patients who referred to the department of the neurology of hospitals of Iran University of Medical Sciences between 1 to 12 months ago were reviewed. Then simple randomize method used. The blind person to the aim of the study, divided the eligible patients into four groups by randomization digits table.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study the assessment will be performed by trained assessors who are blind to the study. After completion of the treatment and completing the assessments, the data

will be entered into the SPSS and analyzed by the blind person about the four treatment groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

The fourth group of this study receives placebo electrical stimulation, As electrodes are first placed on the head And the flow is established And after 30 seconds, the stream fades out.

**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

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Approval date**

2018-05-20, 1397/02/30

**Ethics committee reference number**

IR.IUMS.REC.1398.179

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

Cerebral Vascular Accident

**ICD-10 code**

G46.0

**ICD-10 code description**

Middle cerebral artery syndrome

**2****Description of health condition studied**

Cerebral Vascular Accident

**ICD-10 code**

G46.1

**ICD-10 code description**

Anterior cerebral artery syndrome

**Primary outcomes**

## 1

### **Description**

1-Improvement of executive functions: Spatial Span - One Touch Stockings of Cambridge - latency to correct - mean choices to correct - problem solved on first choices - switching cost - Congruency cost - Stop Signal task - direction errors -Proportion of successful stop - reaction time

### **Timepoint**

One day before the first intervention session and one week after the tenth intervention session.

### **Method of measurement**

Cambridge Neuropsychological Test Automated Battery (CANTAB) test.

## **Secondary outcomes**

## 1

### **Description**

activities of daily living: Those are the skills and tasks that a person pays for them throughout the day and forms the daily routines of the individual's life. These activities include dressing and dressing up, eating, brushing, bathing, going to toilet and dressing yourself. instrumental activities of daily living: These activities are self-care assignments that are usually taught in adolescence and require sophisticated thinking skills, such as the organization of skills. And include activities such as financial management, management of the use of vehicles, purchase of food preparation, traffic management and control how the drugs are.

### **Timepoint**

An initial assessment one day before the start of intervention and a secondary assessment is performed one week after the end of the tenth session of intervention.

### **Method of measurement**

The activities of daily living are assessed by the Barthel index. The instrumental activities of daily living are evaluated by the Lawton scale.

## **Intervention groups**

## 1

### **Description**

Intervention group: Group 1: First tDCS session on c3 or c4, 2 mA current for 20 minutes, then computer based cognitive rehabilitation for 30 to 40 minutes, weekly two sessions and ten sessions totally .

### **Category**

Rehabilitation

## 2

### **Description**

Intervention group: Group 2: First, computer based cognitive rehabilitation for 30 to 40 minutes, and then tDCS on c3 or c4, 2 mA current for 20 minutes, weekly two sessions and ten sessions totally .

### **Category**

Rehabilitation

## 3

### **Description**

Intervention group: Group 3: Simultaneously computer based cognitive rehabilitation for 30 to 40 minutes and tDCS on c3 or c4, 2 mA current for 20 minutes, weekly two sessions and ten sessions totally .

### **Category**

Rehabilitation

## 4

### **Description**

Control group: Group 4: Simultaneously sham tDCS in such a way that the electrical current is applied only for 30 seconds, and then the current is disconnected, and the device is placed somewhere away from the patient's vision and computer based cognitive rehabilitation for 30 to 40 minutes, weekly two sessions and ten sessions totally .

### **Category**

Rehabilitation

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Firuzgar hospital

#### **Full name of responsible person**

Mehdi Nikobakht

#### **Street address**

Beh Afarin St, Karim Khan St, Vali-e-Asr Square, Tehran

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

۱۵۹۳۷۴۷۸۱۱

#### **Phone**

+98 21 8214 1600

#### **Email**

h\_firoozgar@yahoo.com

#### **Web page address**

<http://firoozgar.iums.ac.ir/>

## 2

### **Recruitment center**

#### **Name of recruitment center**

Hazrat E-Rasol Akram Hospital

#### **Full name of responsible person**

Seyyed Hamid Reza Feiz

#### **Street address**

Corner of Mansouri Street - Nayesh St- Sattarkhan- Tehran

#### **City**

Tehran

**Province**  
Tehran  
**Postal code**  
۱۳۴۵۶۱۳۱۳۱  
**Phone**  
+98 21 86709  
**Email**  
PR@iums.ac.ir  
**Web page address**  
[http://hrmc.iums.ac.ir/form\\_contact.php?sid=44&slc\\_lang=fa](http://hrmc.iums.ac.ir/form_contact.php?sid=44&slc_lang=fa)

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Seyed Kazem Malekoti  
**Street address**  
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1449614535  
**Phone**  
+98 21 86709  
**Email**  
PR@iums.ac.ir  
**Web page address**  
<http://iums.ac.ir>

#### Grant name

96-04-32-32633

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran University of Medical Sciences

#### Proportion provided by this source

30

#### 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**  
Institute for Cognitive Science Studies  
**Full name of responsible person**

Susan Samani  
**Position**  
Masters student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Occupational Therapist  
**Street address**  
No 33, East of Zoroaster, above Vali-e-Asr Square, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1413953461  
**Phone**  
+98 21 8880 2063  
**Email**  
susan.samani@gmail.com  
**Web page address**  
<http://www.bacogc.com/>

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Malahat Akbarfahimi  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Occupational Therapist  
**Street address**  
Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Workers' Street, Shah Nazari Street, Mother's square, Mirdamad, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
15459-13478  
**Phone**  
+98 21 2222 7124  
**Email**  
rehab@iums.ac.ir  
**Web page address**  
<http://rehab.iums.ac.ir/>

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Malahat Akbarfahimi  
**Position**

Associated Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapist

**Street address**

Faculty of Rehabilitation Sciences, Iran University of  
Medical Sciences, Workers' Street, Shah Nazari  
Street, Mother's square, Mirdamad, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

15459-13478

**Phone**

+98 21 2222 7124

**Email**

rehab@iums.ac.ir

**Web page address**

<http://rehab.iums.ac.ir/>

## 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