

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Developing a Group Attention Rehabilitation Program and Investigating its Efficacy on Attention and Emotional Outcomes in Patients with Ischemic Stroke

#### Protocol summary

##### Study aim

The Main Purpose: Developing a Group Attention Rehabilitation Program and Investigating its Efficacy on Attention and Emotional Outcomes (Anxiety and Depression) in Patients with Ischemic Stroke

##### Design

A Clinical Trial with a Control Group, with a Parallel Design, Double-Blind, Randomized, on 30 Patients. The Last National Identity Code Number of Patients is used for Randomization

##### Settings and conduct

The Participants are Patients of one or more Neurologists in Tehran. After Review of Records and Referral from the Specialist, and Review of Inclusion and Exclusion Criteria, Eligible Participants are Randomly Assigned to the Study Groups. In this Study, the Experimental Group Receives the Developed Intervention for 10 to 15 Sessions. The Control Group is Active and Receives a General Educational Intervention During the Same Period. Before the Program Starts, After it Finishes, As well as One Month after its Completion, Assessment are Made to Measure the Amount of Possible Changes from Each of the Participants. This Study is Conducted in a Psychological Center Located in Tehran.

##### Participants/Inclusion and exclusion criteria

Patients with Ischemic Stroke who are in a Stable Condition

##### Intervention groups

The Experimental Group will Receive the Target Intervention Which is an Attention Rehabilitation Program and the Control Group will Receive the Educational Intervention Which is simply an Intervention to Inform them about Their Disease and its Course

##### Main outcome variables

Sustained Attention, Selective Attention, Alternating Attention, Divided Attention

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230814059142N1**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

##### Registration date

2023-08-21, 1402/05/30

##### Registrant information

##### Name

Sajjad Montazerghaem

##### Name of organization / entity

Institute for Cognitive Science Studies

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7629 1130

##### Email address

sajjad.montazerghaem@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2023-12-21, 1402/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Developing a Group Attention Rehabilitation Program and Investigating its Efficacy on Attention and Emotional Outcomes in Patients with Ischemic Stroke

### Public title

Developing a Rehabilitation Program in Patients with Stroke

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Having Diagnostic Criteria for Ischemic Stroke Signing the Ethical Consent Form to Participate in the Study (by the person himself/herself or his/her First-Degree Companions) Age between 18 and 65 years Being in the Sub-Acute and Chronic Stage of Stroke, according to Specialist Diagnosis Having the Ability to Read and Write in Persian Obtaining a score of 22 or lower in Montreal Cognitive Assessment (MoCA)

#### Exclusion criteria:

Obtaining a score of 10 or lower in Montreal Cognitive Assessment (MoCA) Having an Unstable Medical Condition, as Diagnosed by a Specialist (eg, Epilepsy or Uncontrolled Diabetes) Having Other Severe Neuro-Cognitive Disorders, as Diagnosed by a Specialist (eg, Aphasia) Drug or Alcohol Addiction Having Movement Limitations that Prevent Training and Intervention Exercises Getting Another Cognitive Rehabilitation Method

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Data analyser

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple Randomization, Based on the Last Digit of the National Identity Code of Each Participant (Even or Odd); Even Numbers will be in the Intervention Group and Odd Numbers will be in the Control Group.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The Main Purpose of this Study and the Provided Interventions are Not Directly Told to the Participants; They are Only Told that the Interventions They Receive are Aimed to Improve their Quality of Life after Stroke. Also, the Participants of Each Group will Not be in Contact with the Other Group. Moreover, the Analyst does Not Know the code of Intervention Which would be Assigned to Each Participant.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Institute for Cognitive Science Studies

##### Street address

Institute for Cognitive Science Studies, Cognitive Science Blvd, Edalat Roundabout, Pardis

##### City

Tehran

##### Province

Tehran

##### Postal code

1658344575

#### Approval date

2023-06-10, 1402/03/20

#### Ethics committee reference number

IR.UT.IRICSS.REC.1402.012

## Health conditions studied

### 1

#### Description of health condition studied

Ischemic Stroke

#### ICD-10 code

I63

#### ICD-10 code description

Cerebral infarction

## Primary outcomes

### 1

#### Description

Sustained Attention

#### Timepoint

Before the Intervention, After the Intervention, 1 Month after the Intervention

#### Method of measurement

Integrated Visual and Auditory Continuous Performance Test - 2 (IVACPT - 2) and Trail Making Test - Part A (TMT-A)

### 2

#### Description

Selective Attention

#### Timepoint

Before the Intervention, After the Intervention, 1 Month after the Intervention

**Method of measurement**

Stroop Test

**3**

**Description**

Alternating Attention

**Timepoint**

Before the Intervention, After the Intervention, 1 Month after the Intervention

**Method of measurement**

Trail Making Test - Part B (TMT-B)

**4**

**Description**

Divided Attention

**Timepoint**

Before the Intervention, After the Intervention, 1 Month after the Intervention

**Method of measurement**

Letter-Number Sequencing Test

**Secondary outcomes**

**1**

**Description**

Anxiety

**Timepoint**

Before the Intervention, After the Intervention, 1 Month after the Intervention

**Method of measurement**

Beck Anxiety Inventory (BAI)

**2**

**Description**

Depression

**Timepoint**

Before the Intervention, After the Intervention, 1 Month after the Intervention

**Method of measurement**

Beck Depression Inventory (BAI)

**Intervention groups**

**1**

**Description**

Intervention group: Group Attention Rehabilitation Program

**Category**

Rehabilitation

**2**

**Description**

Control group: General Education about the Disease and its Course

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Medical Centers of Iran University of Medical Sciences

**Full name of responsible person**

Mohammad Taghi Joghataei

**Street address**

Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway

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**Province**

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**Postal code**

1449614535

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joghataei.mt@iums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Institute for Cognitive Science Studies

**Full name of responsible person**

Javad Hatami

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**Email**

sajjad.montazerghaem@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Institute for Cognitive Science Studies

**Proportion provided by this source**

30

**Public or private sector**

Private

**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**

Sajjad Montazerghaem

**Position**

PhD Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Cognitive Psychology

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Javad Hatami

**Position**

Professor

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**Latest degree**

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**Other areas of specialty/work**

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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