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
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Iran (Islamic Republic of)
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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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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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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