

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effectiveness of computer-based cognitive rehabilitation therapy in improving memory, attention and executive function of patients with dementia after stroke

Protocol summary

Study aim

The effect of computer-based cognitive restoration on improving memory, attention and executive function in patients with dementia

Design

This study was performed as a clinical trial with parallel and randomized groups on 30 patients with dementia due to stroke and these patients were randomly divided into two groups of education and control.

Settings and conduct

First, patients who meet the inclusion criteria will be examined and randomly assigned to the control and experimental groups, and then cognitive rehabilitation will be performed in 15 sessions of 30 minutes at the Baghcheban Cognitive Rehabilitation Clinic in Arak for the experimental group. Finally, the two groups will be evaluated for dependent outcomes.

Participants/Inclusion and exclusion criteria

inclusion criteria : Patients with dementia who have had a stroke for at least 3 months , age 30-70 years old
Non-entry criteria : Having diabetes , Cerebral venous thrombosis , Head and neck injuries , History of chronic heart failure with EF less than 30% , History of dementia medications

Intervention groups

Intervention group: The protocol of cognitive rehabilitation intervention using a computer includes training on the functions of continuous attention, selective attention, focused attention, continuous attention, response inhibition, and short-term memory in each session, respectively. The number of cognitive rehabilitation sessions is 20 30-minute sessions twice a week. This protocol is based on Sulberg & Matter's (2004) Attention Processing Training Protocol. Control group: No educational intervention.

Main outcome variables

In order to perform pre-test and post-test for the

"attention" variable, continuous and simple stropping tests will be used, for the "memory" variable, MoCA and MMSE, and for the "executive performance" variable, the Wisconsin test will be used.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N8**

Registration date: **2022-01-01, 1400/10/11**

Registration timing: **prospective**

Last update: **2022-01-01, 1400/10/11**

Update count: **0**

Registration date

2022-01-01, 1400/10/11

Registrant information

Name

Amin Haji seyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3366 7583

Email address

amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of computer-based cognitive rehabilitation therapy in improving memory, attention and executive function of patients with dementia after stroke

Public title
The effect of computer-based cognitive restoration on improving memory, attention and executive function in patients with dementia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with dementia who have had a stroke for at least 3 months. age 30-70

Exclusion criteria:

Having diabetes Cerebral venous thrombosis Head and neck injuries History of chronic heart failure with EF less than 30% History of dementia medications

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are assigned to two intervention and control groups, respectively, based on the randomization sequence that will be generated beforehand. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate samples. Thus, using block numerical random number generation software, a randomization sequence proportional to the sample size required for the two groups will be generated. Initially, all cases in which the two letters A and B can be arranged in blocks of 8 are produced. A block is then randomly selected from the blocks and the layout pattern in that block will be used to assign participants. This block will then be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups. In fact, the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Arak Branch

Street address

Arak, Imam Khomeini Square, Imam Khomeini Boulevard, 3 km of Khomeini Road, Amirkabir University Town

City

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Province

Markazi

Postal code

3836119131

Approval date

2021-08-29, 1400/06/07

Ethics committee reference number

IR.IAU.ARAK.REC.1400.019

Health conditions studied

1

Description of health condition studied

Stroke dementia

ICD-10 code

F01.51

ICD-10 code description

Vascular dementia with behavioral disturbance

Primary outcomes

1

Description

Attention

Timepoint

Before and after the intervention

Method of measurement

continuous and simple stropping tests

2

Description

Memory

Timepoint

Before and after the intervention

Method of measurement

Montreal cognitive assessment and Mini-Mental state examination

3

Description

executive performance

Timepoint

Before and after the intervention

Method of measurement

Wisconsin test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The protocol of cognitive rehabilitation intervention using a computer includes training on the functions of continuous attention, selective attention, focused attention, continuous attention, response inhibition, and short-term memory in each session, respectively. The number of cognitive rehabilitation sessions is 20 30-minute sessions twice a week. This protocol is based on Sulberg & Matter's (2004) Attention Processing Training Protocol.

Category

Behavior

2

Description

Control group: No educational intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Amir Kabir Hospital

Full name of responsible person

Dr Mostafa Nokani

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Vice Chancellor for Education, Amir Kabir Hospital,
Arak, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Ali Hasani Josheghani

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Rezvan Nemati

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Leila Poursadat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for updating data

Contact

Name of organization / entity

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Position

دانشجو

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

Access will be from 2022/4/20 to 2026/4/20 for 4 years.

To whom data/document is available

University researchers

Under which criteria data/document could be used

If there are any further questions

From where data/document is obtainable

Dr Mostafa Nokani

What processes are involved for a request to access data/document

Letter writing should be done with professors and universities.

Comments