

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The comparison of the effectiveness of cognitive rehabilitation therapy based on brain training, cranial electrical stimulation and their combination on attention, memory, language and visuospatial processing of patients with mild cognitive impairment

Protocol summary

Study aim

Determining the effectiveness of cognitive rehabilitation treatments based on brain training, cranial electrical stimulation and their dual combination on attention, memory, language and visual-spatial processing of patients with MCI. Comparison of the effectiveness of cognitive rehabilitation treatments based on brain training, cranial electrical stimulation and their dual combination on attention, memory, language and visual-spatial processing of patients with MCI.

Design

The research is a single-subject experimental design with multiple baseline and follow-up. Twelve patients are equally assigned to the three groups. The sampling method is Convenience Sampling.

Settings and conduct

The study will be performed on patients with MCI referred to a psychology clinic in Isfahan. The center examiner, statistical analyst, and patients are blinded by the type of intervention of other patients

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Diagnosis of mild cognitive impairment by a psychiatrist 2- Obtaining a quorum score in ACE 3- Not suffering from mental retardation and other types of dementia (Alzheimer's, Lewy bodies, frontotemporal) 5- Not suffering from seizure including epilepsy. Exclusion criteria: 1- Dissatisfaction of the patient or family 2- Occurrence of seizures when receiving cranial electrical stimulation 3- Absence from attending a treatment session

Intervention groups

The first group is just brain training in the form of pencil-paper cognitive assignments. The second group has only electrical cranial stimulation. The third group is the cognitive tasks of pencil-paper and electrical cranial stimulation

Main outcome variables

Increasing and improving patients' scores in the subscales of attention, memory, language and visual-spatial processing based on ACE after the intervention and in the follow-up stage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210320050750N1**

Registration date: **2024-01-31, 1402/11/11**

Registration timing: **retrospective**

Last update: **2024-01-31, 1402/11/11**

Update count: **0**

Registration date

2024-01-31, 1402/11/11

Registrant information

Name

Parisa Pourabadei

Name of organization / entity

The University of Lorestan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-09, 1400/03/19
Expected recruitment end date
 2021-07-22, 1400/04/31
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The comparison of the effectiveness of cognitive rehabilitation therapy based on brain training, cranial electrical stimulation and their combination on attention, memory, language and visuospatial processing of patients with mild cognitive impairment

Public title
 Comparison of the effectiveness of brain training and CES in patients with MCI

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Receive a diagnosis of mild cognitive impairment disorder Get a quorum score on the Addenbrooke's Cognitive Examination-R Not having mental retardation and other types of dementia Not having seizures and epilepsy
Exclusion criteria:
 Dissatisfaction of the patient or her/ his family Occurrence of seizures when receiving cranial electrical stimulation Absence from a treatment session

Age
 To 90 years old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
 Target sample size: 12

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description
 In relation to blinding participants; Patients in each group are interviewed individually before entering the intervention and the treatment is fully explained to them, then the patient is free to sign the consent form or not. At this stage and during the intervention, patients in each group are not aware of the intervention provided for other patients and also none of the patients will be in contact with each other at any stage. In relation to blinding the outcome assessor; The trained Addenbrooke's Cognitive examiner is responsible for

evaluating patients at each stage of the intervention (baseline, intervention, follow-up). The examiner is not aware of the type of intervention presented to the patients and is told to evaluate the referred patients using the Addenbrooke's Cognitive Examination and to provide the therapist with the patient's test score. Therefore, the examiner is responsible for evaluating the referred patients for only 20 minutes and is not aware of the research process and intervention provided for each patient. In relation to data analyzer blinding; Statistical analysis is performed by a statistical expert in such a way that the Addenbrooke test scores in different stages (baseline, intervention, follow-up) are presented to each patient as a separate folder and the statistical specialist is only responsible for drawing the charts. The researcher is responsible for analyzing and interpreting the results and graphs.

Placebo

Not used

Assignment

Factorial

Other design features

Use of clinical cue with the aim of identifying and accurately diagnosing cognitive defects of patients and creating a special treatment protocol for each patient.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research ethics committees of lorestan university of medical sciences

Street address

University of Medical Sciences, Shahid Anoushirvan Rezaei Square, Moalem St., Lorestan, Khorram Abad

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Approval date

2022-07-27, 1401/05/05

Ethics committee reference number

IR.LUMS.REC.1401.120

Health conditions studied

1

Description of health condition studied

Mild cognitive impairment

ICD-10 code

G31.84

ICD-10 code description

Mild cognitive impairment, so stated

Primary outcomes

1

Description

Use them with a score of 87 to 85 in Addenbrooke's Cognitive Examination

Timepoint

In the baseline phase, measure once a week for three weeks, In the measurement intervention phase at the end of sessions 2, 4, 6, 8 and 10 and in follow-up one month after the last session

Method of measurement

Addenbrookes;s Cognitive Exaxmination

Secondary outcomes

1

Description

Attention score on Addenbrooke's cognitive examination

Timepoint

In the baseline phase, measure once a week for three weeks, In the measurement intervention phase at the end of session 2,4,6,8,10 and in follow-up one month after the last session

Method of measurement

Addenbrooke's Cognitive Examination

2

Description

Memory score on the Addenbrooke's Cognitive Examination

Timepoint

In the baseline phase, measure once a week for three weeks, In the measurement intervention phase at the end of session 2,4,6,8,10 and in follow-up one month after the last session

Method of measurement

Addenbrooke's Cognitive Examination

3

Description

Language score on the Addenbrooke's Cognitive Examination

Timepoint

In the baseline phase, measure once a week for three weeks, In the measurement intervention phase at the end of session 2,4,6,8,10 and in follow-up one month after the last session

Method of measurement

Addenbrooke's Cognitive Examination

4

Description

Visual-spatial processing score on the Addenbrooke's Cognitive Examination

Timepoint

In the baseline phase, measure once a week for three

weeks, In the measurement intervention phase at the end of session 2,4,6,8,10 and in follow-up one month after the last session

Method of measurement

Addenbrooke's Cognitive Examination

Intervention groups

1

Description

Intervention group 1: Receiving brain training by pencil-paper method. Pencil-paper exercises are offered for 10 sessions twice a week for 20 minutes.

Category

Rehabilitation

2

Description

Intervention group 2: Receiver of cranial electrical stimulation with intensity of 5 mA and frequency of 350 Hz for 30 minutes for 10 sessions twice a week

Category

Rehabilitation

3

Description

Third intervention group: This group is a double combination of the first and second group interventions. Receiver of 10 sessions of brain training and cranial electrical stimulation session (current of 5 mA and frequency of 350 Hz) as a companion of 30 minutes each session twice a week .

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Saeed Sabbaghipour's office

Full name of responsible person

Saeed Sabbaghipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Lorestan

Full name of responsible person

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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

The University of Lorestan

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**

The University of Lorestan

Full name of responsible person

Parisa Pourabadei

Position

PhD Student of Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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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)

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All research documents including the data file of the participants without name and surname, consent, executive protocol and statistical tables and graphs will

be shared after the end of the study.

When the data will become available and for how long

The access period starts 6 months after the publication of the articles taken out of the study.

To whom data/document is available

All employed researchers and students of domestic and foreign universities

Under which criteria data/document could be used

In order to compare with the results of other similar studies / no other statistical analysis is possible on the presented results.

From where data/document is obtainable

Contact the main researcher (Parisa Pourabadei) via e-mail to: ppourabadi@gmail.com

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

Applicants can send their application to the main researcher (Parisa Pourabadei) by email. They will be answered in less than 72 hours.

Comments