

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effectiveness of Neurofeedback on Working Memory, Cognitive Flexibility and Severity of Patients' Symptoms with Mild Depression

Protocol summary

Study aim

The effectiveness of neurofeedback on working memory, cognitive flexibility and symptom severity in patients with mild depression

Design

The clinical trial has an intervention and control group. The statistical population: 80 people. On 30 patients. Available and randomly (15 people in the experimental group and 15 people in the control group). All complete the questionnaire, only the intervention group is treated with neurofeedback.

Settings and conduct

Research Method: Semi-experimental and pre-test-post-test research design with control group. The statistical population: patients with mild depression in the age range of 20 to 40 years who refer to the psychological clinic of Avae Salamat in Rasht during the first quarter of 1400. Depressed patient during 3 months, twice a week and in each session is followed by neurotherapy for 30 minutes. Patients complete the questionnaire and only the intervention group receives neurofeedback treatment.

Participants/Inclusion and exclusion criteria

Entry requirements: A diagnostic interview was conducted with a 20 to 40-year-old person who referred to Avae Salamat Clinic; If under other medical conditions or with a disorder other than mild depression

Intervention groups

Intervention group: Patients with mild depression under treatment. 15 people in the experimental group and 15 people in the control group. Neurofeedback device and tools such as Beck Depression Inventory, Cognitive Flexibility Questionnaire and Active Memory Questionnaire will be used. Patients complete the questionnaire, only the intervention group under Neurofeedback treatments are included. Neurofeedback therapy is a self-regulatory skill to make the brain more efficient. Ultimately, post-tests are taken from both

groups.

Main outcome variables

Neurofeedback, Working Memory, Cognitive Flexibility, Severity of Patients' Symptoms with Mild Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210611051540N1**

Registration date: **2021-07-10, 1400/04/19**

Registration timing: **prospective**

Last update: **2021-07-10, 1400/04/19**

Update count: **0**

Registration date

2021-07-10, 1400/04/19

Registrant information

Name

Maryam samadi tahergoorabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3334 2933

Email address

maryam.samadi995@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-14, 1400/04/23

Expected recruitment end date

2021-08-19, 1400/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Neurofeedback on Working Memory, Cognitive Flexibility and Severity of Patients' Symptoms with Mild Depression

Public title

Effect of Neurofeedback for the treatment of Depression

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The age of the person is between 20 to 40 years A diagnostic interview has been conducted with the person The person has referred to Avae Salamat Clinic as a patient

Exclusion criteria:

If under other medical conditions If the patient has severe depressive disorder If the patient has a disorder other than depression

Age

From **20 years** old to **40 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

At first, patients are selected according to the inclusion criteria. And then according to the random sequence obtained through Random allocation software In the same way, patients will be randomly divided into experimental and control groups.

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 Lahijan Branch of Azad

University

Street address

Unit9, Mahan building, Amoozgr alley, Hafez street

City

Rasht

Province

Guilan

Postal code

4144891459

Approval date

2021-06-07, 1400/03/17

Ethics committee reference number

IR.IAU.LIAU.REC.1400.017

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

بیماران مبتلا به افسردگی خفیف

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Active Memory Score in the Active Memory Capacity Test by Daneman

Timepoint

Measurement of working memory at the beginning of the study and 10 sessions after starting neurotherapy

Method of measurement

Daneman Active Memory Capacity Test

2**Description**

Cognitive flexibility score in Dena and Vanderwall cognitive questionnaire

Timepoint

Measurement of flexibility at the beginning of the study and 10 sessions after starting neurotherapy

Method of measurement

Cognitive Flexibility Questionnaire Dena and Vanderwall

3**Description**

Depression score in Beck questionnaire

Timepoint

Measurement of the severity of depression at the beginning of the study and 10 sessions after starting neurotherapy

Method of measurement

Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with mild depression who receive neurofeedback treatment. The statistical population of this study will consist of all patients with mild depression who refer to Avaye Salamat psychological clinic during the first quarter of 1400. According to forecasts, the number of these people will be 80. A total of 30 patients will be selected by availability and randomly assigned to two groups (15 in the experimental group and 15 in the control group). In relation to therapeutic intervention and data collection, neurofeedback device treatment protocols and tools such as Beck Depression Inventory, Cognitive Flexibility Questionnaire and Active Memory Questionnaire will be used. Each depressed patient undergoes neurotherapy for 30 minutes 2 times a week for 3 months in each session. All patients complete the questionnaire and only the intervention group is treated with neurofeedback. The effectiveness of neurofeedback depends on the specific area of the brain depending on the type of disorder. In this form, the pattern of brain waves in the disorder is determined first, then the degree of deviation of the waves from the normal pattern is determined, which is done through quantitative electroencephalography. Quantitative electroencephalography is obtained from 19 cranial sites identified according to the 10-20 system, and in fact 19 electrodes are placed on the skull. In fact, we can say that neurofeedback technology response to psychotherapy, cognitive rehabilitation and poor cortical function. It has been used successfully in the treatment of depression, anxiety, post-traumatic stress disorder, personality disorders, addiction, as well as obsessive-compulsive disorder. In this treatment, which is a self-regulatory skill, the brain works more efficiently with the awareness of the person with the disorder through auditory or graphic signals. Based on what has been said in this study, the question is whether neurofeedback has an effect on working memory, cognitive flexibility and the severity of symptoms of patients with mild depression referred to Ava Psychiatric Clinic in Rasht?

Depression Inventory: This questionnaire was developed by Goldberg (1979) and has 18 items in a 5-point Likert scale; Very high (5), high (4), medium (3), low (2), very low (1) and not at all (0) are scored. The minimum and maximum scores of this questionnaire are 18 and 108, respectively, and its cut-off point is 54.

Cognitive Flexibility Questionnaire: This questionnaire was developed by Dennis and Vanderwall (2010) and consists of 20 questions in a 7-point range; I strongly agree to strongly disagree. The questionnaire has three sub-components including; 1) the desire to understand difficult situations as controllable situations, 2) the ability to understand several alternative justifications for human life events and behavior, and 3) the ability to create multiple alternative solutions to difficult situations. This questionnaire has a minimum score of 20, a maximum score of 140 and a cut-off point of 80.

Active Memory

Questionnaire: This questionnaire was developed by Danman and Carpenter (1980) and consists of 27 sentences. These sentences are divided into six parts: two-sentence, three-sentence, four-sentence, five-sentence, six-sentence and seven-sentence. In which part of the test is the two-sentence section to the seven-sentence section read to the subjects, respectively, and they are asked to listen to these sections, each of which contains relatively difficult and unrelated sentences, and then two Do the following: 1- Recognize whether the sentence is semantically correct or not. 2. Write down the last word of each sentence. To score an active memory test, divide the number of correct answers in each section by the total number of sentences, and then add the number obtained from each section and divide it by two, the number obtained indicates the amount of memory capacity. Each subject will be active.

Category

Treatment - Devices

2

Description

Control group: Patients with mild depression who do not receive neurofeedback treatment. The statistical population of this study will consist of all patients with mild depression who refer to Avaye Salamat psychological clinic during the first quarter of 1400. According to forecasts, the number of these people will be 80. A total of 30 patients will be selected by availability and randomly assigned to two groups (15 in the experimental group and 15 in the control group). In relation to data collection, tools such as Beck Depression Inventory, Cognitive Flexibility Questionnaire and Active Memory Questionnaire will be used. All patients complete the questionnaire and only the intervention group will be treated with neurofeedback. The control group will complete the questionnaire twice. Once before the start of treatment in the experimental group and once after the end of treatment in the experimental group.

Depression Inventory: This questionnaire was developed by Goldberg (1979) and has 18 items in a 5-point Likert scale; Very high (5), high (4), medium (3), low (2), very low (1) and not at all (0) are scored. The minimum and maximum scores of this questionnaire are 18 and 108, respectively, and its cut-off point is 54.

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Active Memory Questionnaire: This questionnaire was developed by Danman and Carpenter (1980) and consists of 27 sentences. These sentences are divided into six parts: two-sentence, three-sentence, four-sentence, five-sentence, six-sentence and seven-sentence. Each section of the test is read to the subjects in a two-sentence

section to a seven-sentence section, respectively, and they are asked to listen to these sections, each of which contains relatively difficult and unrelated sentences, and then two Do the following: 1- Recognize whether the sentence is semantically correct or not. 2. Write down the last word of each sentence. To score an active memory test, divide the number of correct answers in each section by the total number of sentences, and then add the number obtained from each section and divide it by two, the number obtained indicates the amount of memory capacity. Each subject will be active.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Avae Salamat Counseling and Psychology Clinic

Full name of responsible person

Naghi Rahnama Nehzomi

Street address

Avae Salamat Counseling and Psychological Clinic,next to Dr. Zahrabi Laboratory, Enghelab St

City

Rasht

Province

Guilan

Postal code

4144794157

Phone

+98 13 3323 0993

Email

maryam.samadi995@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Gholamreza Vaghar Lahijani

Street address

unit9. Mahan building, Amoozegar alley, Hafez street

City

Rasht

Province

Guilan

Postal code

4144794159

Phone

+98 13 3334 2933

Email

maryam.samadi995@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

No

Title of funding source

Lahijan Branch of 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

Maryam Samadi Tahergoorabi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

unit9, Mahan building, Amoozegar alley, Hafez street

City

Rasht

Province

Guilan

Postal code

4144794157

Phone

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Email

maryam.samadi995@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maryam Samadi Tahergoorabi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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City

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Postal code
4144794157
Phone
001333342933
Email
maryam.samadi995@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Maryam Samadi Tahergourabi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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maryam.samadi995@gmail.com
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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

All data obtained from the results of questionnaires, diagnostic interviews and improving the performance of clients will be published.

When the data will become available and for how long

Access period starts from September 2021

To whom data/document is available

Data and other documents are available to all researchers in the field of research

Under which criteria data/document could be used

If other people request to receive data and documents, send a message to my personal email.

From where data/document is obtainable

Applicants should refer to Avae Salamat Clinic located in Rasht, Enghelab Street, next to Zohralabi Pharmacy, to receive the required documents or data. Maryam Samadi Tahergorabi is responsible by calling 09380115195 and emailing maryam.samadi995@gmail.com.

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

Applicants should call 09380115195 to receive the required documents or data or send an email to maryam.samadi995@gmail.com. Documents will be provided to them within 72 hours to a week.

Comments