

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparing the effectiveness of neurofeedback exercises with Mindfulness-Based Cognitive Therapy, in rumination, negative spontaneous thoughts and negative emotion regulation strategies in depression patients; a follow-up period of 6 months

Protocol summary

Study aim

Comparison the effectiveness of neurofeedback exercises with MBCT in rumination, Automatic Negative Thoughts and negative strategies of cognitive emotion regulation in adults with depressive disorder.

Design

Sampling is purposeful and 45 people who get the highest score in the Beck depression questionnaire (1961) are selected as a sample and then randomly assigned to the following three groups: experimental group A, experimental group B and control group C.

Settings and conduct

The research method is applied in terms of purpose, field in terms of location, and semi-experimental in terms of method with a test and retest design with a control group and random assignment. The statistical universe of this research will include all those who referred to psychological clinic of Rahnemon in sep. 2023.

Participants/Inclusion and exclusion criteria

Adults with depressive disorder. Research entry criteria: Obtaining a minimum score of 30 from the Beck depression questionnaire. Non-entry criteria: Not having a physical disorder / Simultaneous use of other therapeutic interventions.

Intervention groups

15 people in experimental group A (neurofeedback exercises), 15 people in experimental group B (cognitive therapy interventions based on mindfulness) 15 people in control group C (without therapeutic interventions)

Main outcome variables

Rumination; automatic negative thoughts; negative strategies of cognitive emotion regulation

General information

Reason for update

Acronym

MBCT

IRCT registration information

IRCT registration number: **IRCT20210618051616N1**

Registration date: **2023-09-27, 1402/07/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-27, 1402/07/05**

Update count: **0**

Registration date

2023-09-27, 1402/07/05

Registrant information

Name

S.Hossein Hassani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4420 6185

Email address

rahnemonclinic@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-16, 1402/06/25

Expected recruitment end date

2023-10-02, 1402/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of neurofeedback exercises with Mindfulness-Based Cognitive Therapy, in rumination, negative spontaneous thoughts and negative emotion regulation strategies in depression patients; a follow-up period of 6 months

Public title

Comparing the effectiveness of neurofeedback with Mindfulness-Based Cognitive Therapy, in depression risk factors; a follow-up period of 6 months

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Obtaining a minimum score of 30 from the Beck Depression Inventory (1961)

Exclusion criteria:

A history of physical disorder that involves mental processes. Simultaneous use of other therapeutic interventions

Age

From **23 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

People who met the entry criteria and were willing to participate in the research are identified. Then, Beck Depression Questionnaire was distributed among the people, 45 people who scored at least 30 from the Beck Depression Questionnaire (1961) were selected as samples. 15 cards are prepared in the name of the experimental group A (related to neurofeedback exercises), 15 cards are prepared in the name of the experimental group B (related to mindfulness-based cognitive therapy) and 15 cards in the name of the control group. After the cards are dealt, the participants will be asked to take one card each and place themselves in their group.

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

islamic azad university- sari branch

Street address

7th km of DARYA road (Farah abad), Sari, Iran

City

Sari

Province

Mazandaran

Postal code

4816419400

Approval date

2022-08-22, 1401/05/31

Ethics committee reference number

IR.IAU.SARI.REC.1401.139

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F32.2

ICD-10 code description

Major depressive disorder, single episode, severe without psychotic features

Primary outcomes

1

Description

RUMINATION

Timepoint

Evaluation before the start of the intervention, the end of the intervention (60 days) and 180 days after the end of the intervention (follow-up)

Method of measurement

Rumination questionnaire (Nalen-Hoeksma and Maro - 1991)

2

Description

Automatic Negative Thoughts

Timepoint

Evaluation before the start of the intervention, the end of the intervention (60 days) and 180 days after the end of the intervention (follow-up)

Method of measurement

Automatic Negative Thoughts questionnaire (Halon and Kendall -1980)

3

Description

Negative Strategies of Cognitive Emotion Regulation

Timepoint

Evaluation before the start of the intervention, the end of the intervention (60 days) and 180 days after the end of the intervention (follow-up)

Method of measurement

Cognitive emotion regulation questionnaire (Garnefski et al. - 2001)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: Neurofeedback Treatment. The experimental group A receives neurofeedback training during 16 regular sessions and in a period of 8 weeks , three sessions in per week. For therapeutic intervention in this research, the Iranian neurofeedback device of the BIOLINE brand will be used, which can be implemented with the help of the computer system and related software (BIOSEES).

Category

Treatment - Other

2

Description

Intervention group B: Mindfulness-Based Cognitive Therapy (MBCT). The experimental group B receives mindfulness treatment during 8 regular sessions and in a period of 8 weeks , 1 session in per week. For therapeutic interventions, the content of the mindfulness-based cognitive therapy sessions compiled by Segal will be used.

Category

Treatment - Other

3

Description

group C: group C (control) will not receive any treatment intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

psychological counseling and services center-
Rahnemon

Full name of responsible person

Seyed Hossein Hassani

Street address

Unit 4, 1th floor, zolfaqar Building, at the entrance of
27th darya alley, taleb amoli street.

City

Amol

Province

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Postal code

4617868391

Phone

+98 11 4420 6185

Email

Rahnemonclinic@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Majid Pourfaraj Omran

Street address

3th km of Neka road , Behshar, Iran

City

Behshahr

Province

Mazandaran

Postal code

4851739869

Phone

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Fax

+98 11 3453 8325

Email

info@iaubeh.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Islamic Azad University

Proportion provided by this source

100

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Psychological counseling and services center-
Rahnemon

Full name of responsible person

Seyed Hossein Hassani

Position

psychotherapist

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Unit 4, 1th floor, Zolfaqar Building, at the entrance of 27th Darya alley, Taleb Amoli street

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Psychological counseling and services center- Rahnemon

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Person responsible for updating data**Contact****Name of organization / entity**

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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

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

There is no further information

When the data will become available and for how long

8 months

To whom data/document is available

Psychologists and psychotherapists

Under which criteria data/document could be used

After analyzing the follow-up period

From where data/document is obtainable

Psychology Clinic of Rahnemon

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

Academic documents and certificates + purpose

Comments