Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+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
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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 updating data

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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