Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Mindfulness Integrated Cognitive behavioral Therapy (MiCBT) on the Negative Emotions, improvement of executive function, Emotion Regulation and change of quantitative electroencephalography waves (QEEG) of patients with Multiple Sclerosis

Protocol summary

Study aim

This study aims to determine the effect of mindfulness training on improving negative emotions, improving executive function, improving cognitive emotional regulation and changing quantitative electroencephalography (QEEG) waves of patients with multiple sclerosis.

Design

The clinical trial has 26 people in the intervention group and 26 people in the control group. It was calculated with Gpower software, with parallel, unblinded, randomized groups.

Settings and conduct

Brain and Neurological Diseases Research Center and Shafa Hospital affiliated to Kerman University of Medical Sciences, Iran

Participants/Inclusion and exclusion criteria

Entering the study is informed consent, having an official diagnosis of MS, women and men 20-50 years old, at least a diploma, right superior and taking beta interferon medication, and exiting the study is suffering from other psychiatric and neurological disorders and taking epilepsy medication and etc

Intervention groups

The intervention group will receive 8 sessions of mindfulness-based cognitive behavioral therapy, MiCBT Kayon 2011, and the control group: the control group will not receive any intervention during the research.

Main outcome variables

Negative emotional states with the DASS21 questionnaire made by Lovibond(1995), emotion regulation with the CERQ questionnaire of Garnefski & Kraaij, executive function with the EFQ questionnaire of Tos Nejati (2013), quantitative electroencephalography waves with brain maps.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230212057396N1**
Registration date: **2023-11-25, 1402/09/04**
Registration timing: **prospective**

Last update: **2023-11-25, 1402/09/04**
Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-31, 1402/10/10

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effectiveness of Mindfulness Integrated Cognitive behavioral Therapy (MiCBT) on the Negative Emotions, improvement of executive function, Emotion Regulation and change of quantitative electroencephalography waves (QEEG) of patients with Multiple Sclerosis

Public title
The Effectiveness of Mindfulness Integrated Cognitive behavioral Therapy (MiCBT) on the Negative Emotions, improvement of executive function, Emotion Regulation and change of quantitative electroencephalography waves (QEEG) of patients with Multiple Sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The criteria for entering the study are all MS patients with an official diagnosis of MS There are men and women with an age range of 20-50 years. They have at least a diploma. The right is superior. They take beta interferon medicine. All patients completed an informed consent form.

Exclusion criteria:
Conditions for not entering the study:MS patients suffer from other psychiatric and neurological disorders. MS patients consumed alcohol or drugs at least two weeks before the study. MS patients received psychological treatment near the study MS patients have epilepsy. They have a history of seizures, brain trauma and other structural brain diseases.

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **52**
More than 1 sample in each individual
Number of samples in each individual: **26**
MS patients under the supervision of a neurologist at Shafa Kerman Hospital will be selected in 2 groups of 26 people with a definite diagnosis of MS with a disability coefficient below 6, the first group will be the intervention group and the second group will be considered the control group. became. The sample size was calculated with Jpower software, for this purpose, in this research, the sample size is selected for each group of 26 people, and the disturbing variables affecting the dependent variable, through the peers of the two groups, in the characteristics that influence the independent variable of the disturbing intervention. We match. In this research, the criteria for entering the study, both groups having informed consent, having an official diagnosis of MS based on the modified McDonald's criteria in 2017 (Mantro, Abit, Balgra et al., 2018), women and men with an age range of 50 - 20 years old, the educational qualification is at least a diploma, right superior, and the use of beta interferon drug, and the exclusion criteria are suffering from other psychiatric and neurological disorders based on medical references and the opinion of a neurologist, a member of the faculty of Kerman University of Medical Sciences. is used, consumption of alcohol or drugs for at least two weeks before the research, receiving any psychological treatment, having epilepsy and history of seizures - taking epilepsy drugs of any name, for example gabapentin for pain relief, taking sleeping pills and barbiturates, history Brain trauma and other structural brain diseases. Before starting the research, the diagnostic interview and DSM5 diagnostic and statistical guide criteria of mental disorders will be used to diagnose the mental disorders of the groups. Participants are randomly assigned to intervention and control groups.

Randomization (investigator's opinion)
Randomized

Randomization description
After reviewing and confirming the criteria for entering and exiting the study, MS patients will be placed in two intervention and control groups of 26 people, so that the names of 26 people who are selected in the lottery will be placed in the intervention group and The rest will be in the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The present research is a semi-experimental design with pre-test and post-test with the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kerman University of Medical Sciences, Iran

Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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Approval date
2023-10-30, 1402/08/08

Ethics committee reference number
IR.KMU.REC.1402.300

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

2

Description of health condition studied
Negative Emotional States
ICD-10 code
R45
ICD-10 code description
Symptoms and signs involving emotional state

3

Description of health condition studied
Executive Functions
ICD-10 code
ICD-10 code description

4

Description of health condition studied
Quantitative Electroencephalographic Waves
ICD-10 code
R94.0
ICD-10 code description
Abnormal results of function studies of central nervous system

5

Description of health condition studied
Emotion Regulation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Negative Emotional States
Timepoint
Emotional states will be measured once before the implementation of the intervention in the first session (pre-test) and once in the last session after the intervention.
Method of measurement
In order to examine emotional states, the original version of DASS has 42 questions, but later it was shortened and reduced to 21 questions. This questionnaire has 21 items including 8 items related to depression (D), 7 items related to anxiety (A) and 6 items related to stress (S).

2

Description
Executive Functions
Timepoint
Executive functions will be measured once before the implementation of the intervention in the first session (pre-test) and once in the last session after the intervention.
Method of measurement
EFQ standard questionnaire of executive functions is used to check executive functions. This questionnaire was compiled by Tos Nejati (2012) and has 30 items and seven subscales. The scoring method is a 5-point Likert scale from almost never (5) to always (1). Its seven subscales include memory (1 to 6), selective attention, questions 7 to 12), decision making (questions 13 to 17), planning (questions 18 to 20), persistent memory (questions 21 to 23), social cognition. (questions 24 to 26) and cognitive flexibility (questions 27 to 30)

3

Description
Quantitative electroencephalographic waves(QEEG)
Timepoint
QEEG will be measured once before the implementation of the intervention in the first session (pre-test) and once in the last session after the intervention.
Method of measurement
An EEG device made in Iran under a Canadian license will be used to record the electroencephalogram. In this method, signals and brain waves are recorded by the electrodes on the scalp. This information is entered into the computer and converted into numbers and graphs through QEEG (quantitative brain mapping).

4

Description
Emotion Regulation
Timepoint
Cognitive emotional regulation will be measured once before the implementation of the intervention in the first session (pre-test) and once in the last session after the intervention.
Method of measurement
CERQ cognitive regulation of emotion questionnaire is used to examine the cognitive regulation of emotion. It is a self-assessment questionnaire designed by Garnevsky and Kraich. This questionnaire has 36 questions that have 9 subscales.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the participants of this group, 8

sessions of Mindfulness Integrated Cognitive behavioral Therapy MiCBT, will be implemented within the framework of the Brauno Cayoun protocol.

Category

Behavior

2

Description

Control group: At the time of conducting the research, the control group will not receive any intervention. The goal is to check whether the passage of time creates a change in these patients or not, but after the completion of the research, the participants of the control group will also receive 8 sessions of MiCBT intervention as an appreciation for conducting the research. will be executed.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

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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

Neurology Research Center

Proportion provided by this source

50

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

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Full name of responsible person

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

the data are collected anonymously

When the data will become available and for how long

in case of request the data are available anonymous

To whom data/document is available

Other researchers have research plans from reputable centers

Under which criteria data/document could be used

researchers with credible studies from reputable constitutions

From where data/document is obtainable

After publication of the article to the corresponding author

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

contact with the corresponding author

Comments