

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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

Name

atefeh fakhrmand

Name of organization / entity

The University of alzahra tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 8804 4040

Email address

a.fakhrmand@alzahra.ac.ir

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

City

Kerman

Province

Kerman

Postal code

7616913555

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 Garnevsy 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**

Shafa Kerman Hospital

Full name of responsible person

Hoda Kamali

Street address

Iran, Kerman, Kausar Blvd., Shafa Medical Education Center

City

Kerman

Province

Kerman

Postal code

۷۶۱۸۷۵۱۱۵۱

Phone

+98 34 3211 5780

Email

Hoda_3303@Yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Neurology Research Center

Full name of responsible person

Ebrahimi-meimand

Street address

Iran, Kerman, Kausar Blvd., Neurology Research Center

City

Kerman

Province

Kerman

Postal code

7618751151

Phone

+98 34 3212 4727

Email

kmu.nrc@gmail.com

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**

The University of Alzahra Tehran

Full name of responsible person

Atefeh Fakhrmand

Position

Phd Student in Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Alzahra University, North Sheikh Bahae St., Deh-e Vanak, Tehran, I. R. of Iran

City

Tehran

Province

Kerman

Postal code

۱۹۹۳۸۹۳۹۷۳

Phone

+98 21 8805 8925

Email

A.Fakhrmand@Alzahra.ac.ir

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

Kerman University of Medical Sciences

Full name of responsible person

Hoda Kamali

Position

Academic staff of Kerman University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Specialized Board of Fellowship MS Specialized Board of Fellowship MS

Street address

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

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5856

Email

Hoda_3303@Yahoo.com

۱۹۹۳۸۹۳۹۷۳

Phone

۹۸۲۱۸۸۰۴۴۰۴۰+

Email

A.Fakhrmand@Alzahra.ac.ir

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

Person responsible for updating data

Contact

Name of organization / entity

The University of AlzahraTehran

Full name of responsible person

Atefeh Fakhrman

Position

PhD Student in psychology

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Alzahra University, North Sheikh Bahae St., Deh-Vanak, Tehran, I. R. of Iran

City

Tehran

Province

Tehran

Postal code