

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effective Of Mindfulness On Perceived Stress, Anxiety, Depression and Quantitative Electroencephalogram(EEG) Parameter's in Parkinson's Patients

Protocol summary

Study aim

Determining the effectiveness of mindfulness on perceived stress, anxiety, depression and quantitative EEG parameters in Parkinson's patients

Design

A clinical trial with a control group, with a parallel group of blind evaluators, randomized on 20 patients. In this design, R represents the random assignment of participants in experimental and control groups.

Settings and conduct

This study will be held in Al-Zahra Hospital (S) in Isfahan city, where the evaluator will be blinded and will not know the results of the tests: instructions on how to practice and integrate mindfulness practice in daily activities, audio file containing mindfulness exercises for 45 minutes (meditation, yoga and body scan) along with instructions for daily practice of mindfulness exercises, 8 sessions per week and 1.5 hours per week

Participants/Inclusion and exclusion criteria

Conditions for entering the intervention: patients 40 to 80 years old who have Parkinson's level 1 and 2 and have not received mindfulness training before and a maximum of one year has passed since the diagnosis of the disease. Conditions for not entering the intervention: patients who are less than 40 years old and more than 80 years old and have been diagnosed with Parkinson's disease for more than a year and at the same time with mindfulness training in educational programs (yoga, meditation) and other sports programs They will attend.

Intervention groups

The experimental group receives interventions related to mindfulness during eight sessions and one 1.5 hour session per week. The control group is without intervention and only pre-test and post-test will be taken from them.

Main outcome variables

Investigating the effect of mindfulness exercises on

perceived stress, anxiety, depression and quantitative EEG parameters in Parkinson's patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220816055723N1**

Registration date: **2022-09-02, 1401/06/11**

Registration timing: **prospective**

Last update: **2022-09-02, 1401/06/11**

Update count: **0**

Registration date

2022-09-02, 1401/06/11

Registrant information

Name

Mahshad Moslemzade

Name of organization / entity

Islamic Azad University of Isfahan(Khorasgan) Branch

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-07, 1401/06/16

Expected recruitment end date

2022-09-17, 1401/06/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effective Of Mindfulness On Perceived Stress, Anxiety, Depression and Quantitative Electroencephalogram(EEG) Parameter's in Parkinson's Patients

Public title

Investigating the effect of mindfulness exercises on Parkinson's patients level 1 and 2

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

The neurologist has confirmed their disease and those who have a conscious desire to participate in the intervention sessions will be selected by announcing the call. As much as possible, the dosage of drugs should be the same during the training period. The person has not received mindfulness training before. Committing to participate in MBSR as many class hours (16 hours) and do homework. have Being 40 to 80 years old A maximum of one year has passed since the diagnosis of the disease Consent of the patient and companions for the participation of the patient in the research

Exclusion criteria:

Age less than 40 years and more than 80 years Patients who have been diagnosed with Parkinson's disease for more than one year. Simultaneous participation in educational programs (yoga, meditation) and sports programs in line with studying during the course

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to intervention and control groups. The block randomization method will be used for the random allocation of patients. We put the software and then the software itself does it.

Blinding (investigator's opinion)

Single blinded

Blinding description

After allocation, it was not possible to keep the trainer blinded to each participant's allocated intervention, but the assessor remained blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Azad University of Khorasgan branch

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University Blvd., Arghvanieh Ave., Eastern Jey Str., Isfahan Town

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Province

Isfahan

Postal code

8155139998

Approval date

2022-07-27, 1401/05/05

Ethics committee reference number

IR.IAU.KHUISF.REC.1401.158

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

parkinsons disease

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes**1****Description**

The amount of perceived stress in people with Parkinson's level 1 and 2.

Timepoint

The first session will be taken at the beginning of the pre-test intervention and the post-test will be taken after eight weeks of intervention.

Method of measurement

To measure perceived stress, Cohen's Perceived Questionnaire (1983) will used

Secondary outcomes**1****Description**

The level of anxiety in people with Parkinson's level 1

and 2

Timepoint

The first session will be taken at the beginning of the intervention and the post-test will be taken eight weeks after the end of the intervention.

Method of measurement

Using Sigmund and Snit Hospital Questionnaire (14 questions) (HADS)

2

Description

The level of depression in people with Parkinson's level 1 and 2

Timepoint

The first session will be taken at the beginning of the intervention and the post-test will be taken eight weeks after the end of the intervention.

Method of measurement

Using Sigmund and Snit Hospital Questionnaire (14 questions) (HADS).

3

Description

Quantitative EEG parameters in people with Parkinson's level 1 and 2

Timepoint

The first session will be taken at the beginning of the Quantitative electroencephalography (qEEG) intervention, and after eight weeks the Quantitative electroencephalography (qEEG) will be taken again.

Method of measurement

In the recording of quantitative EEG parameters before and after the mindfulness intervention for the experimental and control group (without intervention), the 19-channel device of Mitsar company will be used. In this configuration, the WinEEG software receives the amplified, pre-filtered and digitized electrical signals and stores them on the system's storage memory for further processing.

Intervention groups

1

Description

Intervention group: The intervention group receives interventions related to mindfulness during eight sessions and one 1.5 hour session per week. To facilitate the integration of mindfulness into daily life, instructions are provided on how to practice and integrate mindfulness practice into daily activities such as eating, walking, or doing daily tasks.

Category

Rehabilitation

2

Description

Intervention group: The intervention group receives instructions on using mindfulness to cope with stress in daily life. (The audio file contains mindfulness exercises

for 45 minutes (meditation, yoga and body scan) along with instructions for daily practice at home according to the exercises of the sessions and during the course. Time spent in mindfulness exercises It is done weekly for the participants by the mindfulness coach.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra University Hospital

Full name of responsible person

Dr. Ahmad chitsaz

Street address

Isfahan, Shahid Keshvari Highway, Sofe Blvd., Al-Zahra Hospital (S)

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Mahshad Moslemzade

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**

Persons

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

Islamic Azad University

Full name of responsible person

Mahshad Moslemzade

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Others

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

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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

Not applicable

Title and more details about the data/document

The provided files are in the form of a complete Excel file, in which the patients' history, the level of the disease and the duration of the disease, as well as the drugs used, the underlying diseases, the history of surgery and the history of Parkinson's disease are described. The informed consent form was designed and It will be available to each participant. After completing the intervention steps, a full report of the clinical interventions will be prepared and will be accessible in the file as a document.

When the data will become available and for how long

The Excel file of the participants' profile can be accessed after completion and before the intervention. The informed consent form will be available in the first

session after the intervention, when all participants have signed. The clinical interventions file will be in the last session of the intervention and after The result and approval of the relevant judges and professors will be available after printing.

To whom data/document is available

People related to this research will be allowed access. such as supervisors and advisors and referees. Apart from the details of the participants, other researchers working in academic and scientific institutions will have the necessary access.

Under which criteria data/document could be used

Access to all parts of this study will be granted solely for treatment and to supplement and improve research.

From where data/document is obtainable

To access this information, they can refer to the email address i.sajjadian@khuif.ac.ir and mahshadmoslemzade70@gmail.com.

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

Applicants can access the information after one working week after entering the email to the entered email address.

Comments