Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 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

Iran (Islamic Republic of)

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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
Street address
University Blvd., Arghvanieh Ave,. Eastern Jey Str., Isfahan Town
City
Esfahan
Province
Isfehan
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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Esfahan

Province

Isfehan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Majid Toghiyani

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University Blvd-Arghvanieh Blvd-Eastern Jey St-Esfahan Town

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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
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Person responsible for updating data

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Other areas of specialty/work
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Isfehan
Postal code
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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@khuisf.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