

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the effectiveness of Mindfulness with usual parkinson treatment on quality of life among individuals with Parkinson's Disease

Protocol summary

Study aim

Determining the impact of Mindfulness on quality of life among individuals with Parkinson's disease

Design

This study is a randomized parallel-group clinical trial with control group which is done On 40 patients with Parkinson's disease

Settings and conduct

This study will be conducted at Tabriz health centers. The sample size in this clinical trial is 40 and the study population is consisted of Parkinson patients, That these patients will be divided into two control (20 patients) and Intervention groups (20 patients) using table of random numbers. All of the patients will receive usual medication too. The patients in Mindfulness Based Stress Reduction group are participated in 8 therapy sessions. Participants of both groups will fill out the 39-Item Parkinson's Disease Questionnaire (PDQ-39) Before and after intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of Parkinson's Disease based on the UK Brain Bank Criteria; Patients with Hoen and Yahr degree of 1-3; Regular treatment of Parkinson's disease with the related drugs. Non inclusion criteria : The need to adjust the dose of Parkinson's drug in the last three months (before entering the study); Having an unstable or life-threatening illness.

Intervention groups

Intervention group: The intervention in this study will be two-hour Mindfulness sessions which will be held weekly for 8 weeks. These meetings will be held in the groups of 4 to 5 people. Control group : In the control group, the routine treatment of patients will continue.

Main outcome variables

PDQ-39 index score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181007041258N1**

Registration date: **2018-11-20, 1397/08/29**

Registration timing: **retrospective**

Last update: **2018-11-20, 1397/08/29**

Update count: **0**

Registration date

2018-11-20, 1397/08/29

Registrant information

Name

Reza Rikhtehgarghiasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 3374

Email address

rikhtehgar.r@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-10-26, 1397/08/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Mindfulness with usual parkinson treatment on quality of life among individuals with Parkinson's Disease

Public title

Effect of Mindfulness in Parkinson

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Parkinson's Disease based on the UK Brain Bank Criteria. Patients with Hoen and Yahr degree of 1-3
Regular treatment of Parkinson's disease with related drugs

Exclusion criteria:

The need to adjust the dose of Parkinson's drug in the last three months (before entering the study) Having an unstable or life-threatening illness

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

The tool for randomization in this study was statistical software

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

Tabriz University of Medical Sciences

Street address

Golgasht Street, Azadi Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2018-09-24, 1397/07/02

Ethics committee reference number

IR.TBZMED.REC.1397.551

Health conditions studied

1

Description of health condition studied

Parkinson's disease

ICD-10 code

G20

ICD-10 code description

Parkinson disease

Primary outcomes

1

Description

PDQ39 index

Timepoint

before and 8 weeks after intervention

Method of measurement

PDQ39 standard questionnaire

Secondary outcomes

1

Description

PDQ39 index score

Timepoint

8 weeks later

Method of measurement

Standard questionnaire

Intervention groups

1

Description

Intervention group : will complete eight sessions of the Mindfulness course in two months (every week a two-hour session) . In first to fourth sessions, the main techniques are taught based on mindfulness, including mindfulness of body feeling , practicing of physical inspection, mindfulness of breathing, body, sounds and objects, mindfulness of daily activities, trying to look or listen for five minutes and mindfulness of mental events (focus on thoughts as irrational beliefs, focus on the emotions as experience of the anxiety caused by irrational belief and mental images, and finally learn how anxiety and worry influence on daily treatment by different exercise). In the fifth to eighth sessions, while continuing the review of previous practice, other techniques, such as mindfulness training related mood, thoughts, attitudes, thought and feelings practice and pleasant and unpleasant events calendar will be taught.

Category

Behavior

2

Description

Control group: Control group will receive the usual Parkinson treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Neda Ghaemian

Street address

Daneshghah street

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nedaqman@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Neuroscience Research Center

Street address

Azadi Street

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nsr2008@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

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

Tabriz University of Medical Sciences

Full name of responsible person

Neda Ghaemian

Position

Resident of Neurology

Latest degree

Medical doctor

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is not more information

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