

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The Effect of Mindfulness-Based Stress Reduction on Restless Legs Syndrome in Hemodialysis Patients

Protocol summary

Study aim

Determining the effect of Mindfulness-Based Stress Reduction on Restless Legs Syndrome in Hemodialysis Patients

Design

A randomized, parallel group, controlled trial

Settings and conduct

The study was designed to "determine the effect of mindfulness-based stress reduction on restless legs syndrome in hemodialysis patients in hospitals affiliated with Kashan University of Medical Sciences."

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range of 18 to 65, lack of peripheral neuropathy, lack of psychiatric illness, full awareness, lack of cognitive disorder, reading and writing skills, Lack of vision and hearing problems, having six months on hemodialysis history. Exclusion criteria: Under treatment with psychotherapy, Presence of another neurological disease, Iron deficiency anemia, Unconsciousness no restless legs syndrome

Intervention groups

Sixty hemodialysis patients with restless leg syndrome were assigned in control and intervention group randomly. The Mindfulness-Based Stress Reduction group received eight weekly treatments. Each session was 60 min. The sessions were based on Kabat-Zinn protocol.

Main outcome variables

Severity of restless legs syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130721014086N13**

Registration date: **2020-07-28, 1399/05/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-28, 1399/05/07**

Update count: **0**

Registration date

2020-07-28, 1399/05/07

Registrant information

Name

Mohammad Aghajani

Name of organization / entity

Kashan University of Medical Sciences

Country

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aghajani_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Mindfulness-Based Stress Reduction on Restless Legs Syndrome in Hemodialysis Patients

Public title

Effect of Mindfulness-Based Stress Reduction on Restless Legs Syndrome in Hemodialysis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hemodialysis patients with restless legs syndrome Age range 18 to 65 Hb >10 mg/dl Lack of peripheral neuropathy Having full awareness Lack of cognitive disorder like dementia and Alzheimer Reading and writing skills Lack of vision and hearing problems At least 6 months of dialysis history No psychiatric illness

Exclusion criteria:

Under treatment with psychotherapy Presence of another neurological disease Iron deficiency anemia Unconsciousness no restless legs syndrome

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were assigned to two groups of intervention and control in the form of four and six blocks.randomization is done by using computer and random digit table.

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**

Kashan University of medical Science

Street address

Ghotbe Ravadi, Kashan

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Province

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Postal code

88715973474

Approval date

2020-06-27, 1399/04/07

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1399.024

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

Restless leg syndrome

ICD-10 code

G25.81

ICD-10 code description

Restless legs syndrome

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

Restless leg syndrome severity

Timepoint

Before study and 1 month later

Method of measurement

International standard restless leg syndrome questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:The 8 weekly sessions followed the standard MBSR protocol as developed by Kabat-Zinn (1990). Each session was 60 min. The overall content of the sessions were:1)Introducing mindfulness 2)Sitting Meditation 3)Body Scan and walking meditation 4)yoga 5)Mindfulness of feelings and physical pain, meditation in every day of life 6)Self-reflection and self-management 7)Acceptance and changing 8)How can I take the best care of myself?

Category

Behavior

2**Description**

Control group: patients receive usual treatments and educational pamphlets

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Akhavan Hospital

Full name of responsible person

Zahra Delshad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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research@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Aghajani

Position

lectuerer

Latest degree

Master

Other areas of specialty/work

Nursery

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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

No 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