Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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:ˊAge range of 18 to 65, lack of peripheral nouropathy, 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
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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 nouropathy 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
Isfehan
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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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