Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Randomized controlled trial the effectiveness of Mindfulness-Based Stress Reduction program on Depression, Anxiety and Quality of life of hemodialysis patients

Protocol summary

Summary

(1) Objectives: This study aimed to evaluate the effectiveness of Mindfulness based stress reduction (MBSR) program on depression,anxiety and quality of life of hemodialysis patients at kashan.(2) Design: General plan of this study is consisted of experimental pre-test and post-test.(3) Setting and conduct: 40 hemodialysis patient who are able to complete the program will be selected by convenient sampling and will be randomly assigned in two groups(treatment as usual hemodialysis group that receiving health education courses and the second group that, in addition to these,receive Mindfulness-based stress reduction program.patients in both groups first be studied for cognitive level by clinical interview and MMSE test and if met the inclusion criteria of study,filled out Hospital Anxiety and depression scale(HADS),quality of life short form-36(SF-36), Mindfulness 15-item questionnaire as pre-test and post-test.(4) Interventions: intervention is consist of courses of health education for both groups and 8 sessions (each session is 120 minutes) of Mindfulness based stress reduction just for experimental group.(5) Main outcome measures: Main outcome measures variables in this research are anxiety, depression,mindfulness and quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081723652N1**
Registration date: **2015-09-17, 1394/06/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-17, 1394/06/26

Registrant information

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Mostafa Haghshenas
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

Expected recruitment start date

2015-09-01, 1394/06/10

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized controlled trial the effectiveness of Mindfulness-Based Stress Reduction program on Depression, Anxiety and Quality of life of hemodialysis patients

Public title

effectiveness of Mindfulness-Based Stress Reduction

program on Depression, Anxiety and Quality of life of hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria
inclusion criteria:all of hemodialysis patients at least one year on hemodialysis treatment,at least elementary education level,at least 2 hemodialysis program in week, each hemodialysis duration at least 3 hours,age between 18-60 years,Consent to participate in the study by completing the informed consent form,of both sexes male and female.exclusion criteria:patient unwillingness to stay,suicidal ideation,active psychotic symptoms,Having a categorical diagnosis of psychiatric disorders and Regular medical or psychological treatment,age below 18 and more than 60 year,lack of minimal literacy,severe mental disorders

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Ethics committee of Kashan University of Medical Sciences and Health Services

Street address
Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan, Iran

City
Kashan

Postal code
8715988141

Approval date
2015-05-22, 1394/03/01

Ethics committee reference number
IR.KAUMS.1394.36

Health conditions studied

1

Description of health condition studied
end stage renal disease

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

2

Description of health condition studied
depression

ICD-10 code
F32

ICD-10 code description
Depressive episode

3

Description of health condition studied
anxiety

ICD-10 code
F41

ICD-10 code description
Other anxiety disorders

Primary outcomes

1

Description
anxiety

Timepoint
before intervention, After intervention

Method of measurement
hospital anxiety and depression scale

2

Description
depression

Timepoint
before intervention, After intervention

Method of measurement
hospital anxiety and depression scale

3

Description
quality of life

Timepoint
before intervention, After intervention

Method of measurement
short form quality of life SF-36

4

Description
mindfulness
Timepoint
before intervention, After intervention
Method of measurement
Mindfulness 15-item questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Mindfulness Based Stress Reduction; 8 sessions; 2 hours, intervention group
Category
Behavior

2

Description
health education,intervention and control group
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Kargarnejad Hospital
Full name of responsible person
Dr Fatemeh Ghoreishi
Street address
Kargarnejad Hospital, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Kashan University of Medical Sciences and Health Services
Full name of responsible person
Dr Qolam Ali Hamidi
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Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan
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Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Kashan University of Medical Sciences and Health Services
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences and Health Services
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty