

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

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

Protocol summary

2015-09-17, 1394/06/26

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

Registrant information

Name

Mostafa Haghshenas

Name of organization / entity

Kashan University of Medical Sciences and Health Services

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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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Kashan

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

Street address

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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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

Full name of responsible person

Mostafa Haghshenas

Position

Resident of Psychiatry

Other areas of specialty/work

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Person responsible for updating data

Contact

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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