

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 0021

##### Email address

haghshenas2005@gmail.com

#### 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

IR.KAUMS.1394.36

## 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

## 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

**City**

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

**City**

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

**Full name of responsible person**

Mostafa Haghshenas

**Position**

Resident of Psychiatry

**Other areas of specialty/work****Street address**

Kargarnejad Hospital, Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan

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**Web page address**

### Person responsible for scientific inquiries

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## Person responsible for updating data

### 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**  
**Street address**  
Kargarnejad Hospital, Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan  
**City**  
Kashan

## 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*