Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of mindfulness program on general health of patients treated with hemodialysis in Isfahan selected hospitals in 2017

Protocol summary

Summary

The present study aimed to investigate the effect of mindfulness program on general health among patients treated with hemodialysis.This research was a clinical trial which selected 60 patients treated with hemodialysis who were eligible for the study and determined the level of their general health. These patients were divided into two experimental and control groups. The experimental group received 8 training sessions of mindfulness skills while the control group received 8 training sessions associated with end-stage renal failure and hemodialysis without being exposed to any mindfulness concept. Training sessions for both groups were carried out in the second 30 minutes after initiation of dialysis in six 1-hour individual sessions and two 1.5-hour plenary sessions. The mean score of general health and its subscales (physical symptoms, anxiety symptoms and sleep disturbances, social dysfunction and depression symptoms) were compared in each group and between the two groups before, immediately after and one month after the intervention. Data collection tool was General Health Questionnaire (GHQ). Data analysis was performed using SPSS v. 20, chi-square test, repeated measures ANOVA and independent t-test.

General information

Acronym

Mindfulness

IRCT registration information

IRCT registration number: **IRCT2017053134263N1**
Registration date: **2017-06-15, 1396/03/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-15, 1396/03/25

Registrant information

Name

Maryam Mosavinejad Naeini

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3786 1027

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-01-09, 1395/10/20

Expected recruitment end date

2017-01-24, 1395/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness program on general health of patients treated with hemodialysis in Isfahan selected hospitals in 2017

Public title

The effect of mindfulness on general health in patients treated with hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:Patients age are between 18 to 65;

Hemodialysis onset 3 months at least; Hemodialysis do 3 times a week;They shouldn’t participate in any complementary treatments during this study; Over the past year, according to medical records, do not diagnose depression or other mental illness for them;They shouldn’t be treated with Psychiatry and Psychotherapy;They don’t have any intellectual or physical disability;Having full consciousness, acceptable hearing and speaking ability to answer the questions Exclusion criteria:Absent in two or more hope therapy sessions during study;Patients who giving kidney graft or going under peritoneal dialisys;Patients who don’t like to participate in every level of study;Patients start taking drugs to control depression, anxiety and stress in order of physician;Death

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
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
Isfahan University of Medical Sciences
Street address
Hezarjirib street, Isfahan University of Medical Sciences
City
Isfahan
Postal code
Approval date
2017-01-28, 1395/11/09
Ethics committee reference number
11/4864/د

Health conditions studied

1

Description of health condition studied
hemodialysis
ICD-10 code
Z49.1
ICD-10 code description
Extracorporeal dialysis

Primary outcomes

1

Description
Physical symptoms
Timepoint
Before, after and 1 month after intervention
Method of measurement
GHQ-28

2

Description
Anxiety symptoms and sleep disturbances
Timepoint
Before, after and 1 month after intervention
Method of measurement
GHQ-28

3

Description
Social dysfunction
Timepoint
Before, after and 1 month after intervention
Method of measurement
GHQ-28

4

Description
Depression symptoms
Timepoint
Before, after and 1 month after intervention
Method of measurement
GHQ-28

5

Description
General health
Timepoint
Before, after and 1 month after intervention
Method of measurement
GHQ-28

Secondary outcomes

1

Description
The effect of mindfulness program on the general health
Timepoint

Before, after and 1 month after intervention

Method of measurement

GHQ-28

Intervention groups

1

Description

The experimental group received 8 training sessions of mindfulness skills.Training sessions were carried out in the second 30 minutes after initiation of dialysis in six 1-hour individual sessions and two 1.5-hour plenary sessions.

Category

Behavior

2

Description

The control group received 8 training sessions associated with end-stage renal failure diseases and hemodialysis without being exposed to any mindfulness concept.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor and Aliasghar Hospital

Full name of responsible person

Fariba Taleghani

Street address

Isfahan University of Medical Sciences

City

Isfahan

2

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

Fariba Taleghani

Street address

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City

Isfahan

3

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Fariba Taleghani

Street address

Isfahan University of Medical Sciences

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Fariba Taleghani

Street address

Hezarjirib street, Isfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences

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

Isfahan University of Medical Sciences

Full name of responsible person

Maryam Moosavinejad Naeini

Position

MSc in Nursing Education

Other areas of specialty/work

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Person responsible for scientific

inquiries

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College of Nursing and Midwifery, Isfahan University of Medical Sciences

Full name of responsible person
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Position
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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