

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of meditation on hemodialysis adequacy and its psychological complications among patients undergoing hemodialysis

Protocol summary

Summary

Objectives: 1- To investigate the effect of meditation on hemodialysis adequacy among patients undergoing hemodialysis 2- To investigate the effect of meditation on some psychological complications of hemodialysis (Depression, anxiety, stress) among patients undergoing hemodialysis. Design: This study was conducted as a clinical trial. Setting and Conduct: All patients undergoing hemodialysis hospitalized in the two hospitals affiliated to Zanjan University of Medical Sciences including Emdadi hospital in Abhar and Boo Ali hospital in Khorramdarreh were recruited to the study based on the inclusion criteria. Using the table of random numbers we will allocate the patients to two intervention and control groups. Data will be measured using the Stress Anxiety Depression Scale-21 (DASS-21) and the dialysis adequacy scale. Participants including major eligibility criteria: All 67 patients with hemodialysis hospitalized in the two hospitals affiliated to Zanjan University of Medical Sciences will be recruited to the study. The inclusion criteria include diagnosed with chronic kidney disease by their physicians; being under hemodialysis for at least three months; not having participated in other intervention studies; ability to participate in training sessions; ability to do meditation exercises; being registered in the hospital; lack of previous experiences with meditation; and lack of specific medical prohibitions, such as deafness, blindness, end-stage heart failure, brain trauma, uncontrolled hypertension and acute glaucoma; being consent to participate in the study; Lack of psychological drug use; lack of proved psychological disease. The exclusion criteria include unable or unwilling to participate in a group program; having reduced cognitive ability; hospitalized because of other medical conditions; having contraindications for doing meditation exercises; kidney transplantation during the study or referring to other hospitals; fistula or graft damages; and using psychological medications during the study. Intervention:

The intervention is the "Two Heart" meditation (meditation of love and kindness to all the land) program. The program comprises three 15- to 20-minutes educational practice sessions weekly offered over an eight-week period. Main outcome measures(variables): Changes in depression, anxiety, and stress symptoms during the first two months will be considered.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102917454N3**

Registration date: **2014-12-07, 1393/09/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-07, 1393/09/16

Registrant information

Name

kourosh Amini

Name of organization / entity

Zanjan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 243377251314

Email address

korosh@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanjan University of Medical Sciences

Expected recruitment start date

2014-11-11, 1393/08/20

Expected recruitment end date

2015-02-09, 1393/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of meditation on hemodialysis adequacy and its psychological complications among patients undergoing hemodialysis

Public title

Effect of meditation on hemodialysis adequacy and some psychological symptoms

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria: diagnosed with chronic kidney disease by their physicians; being under hemodialysis for at least three months; not having participated in other intervention studies; ability to participate in training sessions; ability to do meditation exercises; being registered in the hospital; lack of previous experiences with meditation; and lack of specific medical prohibitions, such as deafness, blindness, end-stage heart failure, brain trauma, uncontrolled hypertension and acute glaucoma; being consent to participate in the study; Lack of psychological drug use; lack of proved psychological disease. The exclusion criteria include unable or unwilling to participate in a group program; having reduced cognitive ability; hospitalized because of other medical conditions; having contraindications for doing meditation exercises; kidney transplantation during the study or referring to other hospitals; fistula or graft damages; and using psychological medications during the study.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **67**

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 the Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi Blvd., Zanjan, Iran

City

Zanjan

Postal code**Approval date**

2013-09-23, 1392/07/01

Ethics committee reference number

ZUMS.REC.1392.49

Health conditions studied**1****Description of health condition studied**

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

2**Description of health condition studied**

Depression

ICD-10 code

F32.9

ICD-10 code description

Depressive episode, unspecified

3**Description of health condition studied**

Stress

ICD-10 code

Z73.3

ICD-10 code description

Stress, not elsewhere classified

Primary outcomes**1****Description**

Anxiety

Timepoint

Before the intervention, four weeks after the intervention and after 8 weeks of intervention

Method of measurement

Depression, Anxiety, Stress Scale- 21 (DASS-21)

2

Description

Depression

Timepoint

Before the intervention, four weeks after the intervention and after 8 weeks of intervention

Method of measurement

Depression, Anxiety, Stress Scale- 21 (DASS-21)

3

Description

Stress

Timepoint

Before the intervention, four weeks after the intervention and after 8 weeks of intervention

Method of measurement

Depression, Anxiety, Stress Scale- 21 (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description

The program comprises three 15- to 20-minutes educational practice sessions weekly offered over an eight-week period. Half an hour before starting dialysis, patients will attend in a room located in the dialysis unit with the facilities including chair, enough space. The Two Hearts meditation exercises (meditation of love and kindness to all the land) will commence by a trained tutor to the intervention group. The duration of the meditation will last 15-20 minutes. The trained tutor will be available during the program.

Category

Behavior

2

Description

In order to decrease the investigator bias, the tutor and the researcher will attend the control group half an hour once a week and will discuss the dialysis and their related problems.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Emdadi hospital of Abhar city

Full name of responsible person

Sahar Dehgani

Street address

Emdadi hospital of Abhar, Khoramshar Boulevard, Abhar, Zanjan

City

Abhar

2

Recruitment center

Name of recruitment center

Bu-Ali hospital of Khoramdareh city

Full name of responsible person

Maryam Mohammadi

Street address

Bu-Ali hospital of Khoramdareh, Imam St, Khoramdareh, Zanjan

City

Khoramdareh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zanjan University of Medical Sciences

Full name of responsible person

Research administrator of university, Mohammad Masoud Vakili

Street address

Zanjan University of Medical Sciences, Azadi Blvd., Zanjan, Iran

City

Zanjan

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, Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Kourosh Amini

Position

Assistant Professor/ PhD in Nursing

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

School of Nursing and Midwifery, Zanjan University of Medical Sciences, Parvin Etesami Street, Zanjan, Iran

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Postal code**Phone**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Web page address**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