

# 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

**City**

Zanjan

**Postal code****Phone**

+98 24337751314

**Fax****Email**

korosh@zums.ac.ir

**Web page address****Person responsible for scientific 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**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Postal code****Phone**

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**Fax****Email**

korosh@zums.ac.ir

**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*