

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of the effect of guided imagery and routine care on Anxiety and Quality of sleep among hemodialysis patients

#### Protocol summary

##### Summary

The aim of this study will be to determine the effect of Guided imagery compared with routine care on anxiety and quality of sleep among hemodialysis Patients. Some items of inclusion criteria included: patients at the age of 18 to 70 years; having full consciousness and Hemodialysis history for at least 2 months. Also, some exclusion criteria included: if the patients suffer from Severe physical disease or unable to collaborate. In this randomized clinical trial, 70 patients undergoing hemodialysis in Akhavan Hospital at Kashan city will be assigned into intervention and control groups through block randomization in 2017. After initial selection of samples, demographic data form and STAI anxiety and PSQI quality of sleep questionnaire will be completed in both groups. In the intervention group, in addition to the routine care, guided visualization CD which will be prepared by the researcher and last about 25 minutes, will be played and patients listen to them through headphones. Guided visualization includes visualization of the beautiful and pleasant scenery (the beach) and positive inspiration which is associated with increased wellness. Intervention group will receive mentioned interventions 2 times a day, in the morning (between 8 and 9 am) and at night (between 20 and 21 pm), for 4 weeks. The control group will receive routine care. Four weeks after the end of the intervention, STAI anxiety and PSQI quality of sleep questionnaire will be completed again for both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016120931312N1**

Registration date: **2017-01-06, 1395/10/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-01-06, 1395/10/17

##### Registrant information

###### Name

Abbas Mohsenzadeh

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5554 0021

###### Email address

mohsenzadeh-a@kaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Kashan University of Medical Sciences

##### Expected recruitment start date

2017-01-07, 1395/10/18

##### Expected recruitment end date

2017-03-15, 1395/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of guided imagery and routine care on Anxiety and Quality of sleep among hemodialysis patients

##### Public title

The Effect of Guided imagery on Anxiety and Quality of sleep of Hemodialysis Patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: patients at the age of 18 to 70 years old; having full consciousness; not having hearing loss; Patients' willingness to participate in clinical trials; Hemodialysis history for at least 2 months; absence of opium addiction history; not participation in guided imagery sessions in the past. Exclusion criteria: suffer from a severe physical disease; hospitalization and undergoing surgery; not willing to participate in the study.

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

The method of choice for randomization in this study is block randomization.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

##### Street address

Kashan University of Medical Sciences, 5th kilometer of Qotb -e Ravandi Blvd, Kashan Kashan

##### City

Kashan

##### Postal code

87135/1416

#### Approval date

2016-11-08, 1395/08/18

#### Ethics committee reference number

IR.KAUMS.REC.1395.80

## Health conditions studied

### 1

#### Description of health condition studied

anxiety

#### ICD-10 code

F40

#### ICD-10 code description

Phobic anxiety disorders

## Primary outcomes

### 1

#### Description

anxiety

#### Timepoint

before the intervention and 4 week after the intervention

#### Method of measurement

STAI Anxiety questionnaire

### 2

#### Description

quality of sleep

#### Timepoint

before the intervention and 4 week after the intervention

#### Method of measurement

PSQI quality of sleep questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: intervention group will listen to the Guided Imagery CD which is prepared by the researcher by using a CD player and headphones for 25 minutes, 2 times a day in the morning (between 8 and 9 am) and at night (between 20 and 21 pm) for 4 weeks, in addition to routine care.

#### Category

Other

### 2

#### Description

Control group: they will receive only routine care.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Akhavan hospital  
**Full name of responsible person**  
Mohammad Afshar  
**Street address**  
Akhavan hospital, in front of Municipality, Abazar  
Avenue, Kashan  
**City**  
Kashan

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Afshar\_m\_1343@yahoo.com;  
Mohammad.Afshar@modares.ac.ir  
**Web page address**  
www.kaums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice chancellor for research, Kashan University of  
Medical Sciences  
**Full name of responsible person**  
Gholamali Hamidi  
**Street address**  
Kashan University of Medical Sciences, 5th kilometer  
of Qotb -e Ravandi Blvd, Kashan 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, Kashan 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**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Mohammad Afshar  
**Position**  
PhD/ assistance professor  
**Other areas of specialty/work**  
**Street address**  
Kashan University of Medical Sciences, 5th kilometer  
of Qotb -e Ravandi Blvd, Kashan Kashan  
**City**  
Kashan  
**Postal code**  
87135/1416  
**Phone**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
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**Web page address**  
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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*