

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
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Kashan

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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
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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
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Person responsible for updating data

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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