

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of guided imagery on hospital anxiety and depression and hemodynamic parameters in patients undergoing hemodialysis

Protocol summary

Summary

The aim of this study was the effects of guided imagery on anxiety, depression, fatigue and hemodynamic parameters in patients undergoing hemodialysis. In this randomized clinical trial, 80 hemodialysis patients were randomly allocated to two groups guided imagery and control (40 patients in each group). The study will be conducted on hemodialysis patients admitted to Rajaei Hospital in Karaj. In intervention group, patients will listen CD of guided imagery for 20 minutes. Interference will not occur in the control group. Before the intervention, after intervention, 30 minutes after intervention, and at the end of hemodialysis anxiety, depression, fatigue, and hemodynamic parameters are measured and recorded. The researchers and data monitoring committee will not become aware of what sort of intervention the patients have been received

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512077529N9**

Registration date: **2015-12-20, 1394/09/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-20, 1394/09/29

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3071

Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed University Vice chancellor for research

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-03-10, 1394/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of guided imagery on hospital anxiety and depression and hemodynamic parameters in patients undergoing hemodialysis

Public title

Effect of guided imagery on the level of anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: the desire to participate in the study; the absence of cognitive impairment or impaired cognitive function of patients; not having hearing impairment; ability reading and writing; aged between 35 and 70 years, having high anxiety and depression scores of 7 tools HADS. Exclusion criteria: condition of hemodynamic is unstable; transfer of patient to another ward; patient dissatisfaction to continue participation in the study.

Age

From **35 years** old to **70 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran.

City

Tehran

Postal code

Approval date

2015-11-16, 1394/08/25

Ethics committee reference number

Shahed.REC.1394.64

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Depressive episode

2

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 in first session and in final any sessions Before , after the intervention, 30 minutes after intervention, and after finish of the hemodialysis

Method of measurement

anxiety and depression scale (HADS)

2

Description

Depression

Timepoint

Before the intervention in first session and in final any sessions Before , after the intervention, 30 minutes after intervention, and after finish of the hemodialysis

Method of measurement

anxiety and depression scale (HADS)

3

Description

Fatigue

Timepoint

Before the intervention in first session and in final any sessions Before , after the intervention, 30 minutes after intervention, and after finish of the hemodialysis

Method of measurement

Brief Fatigue Inventory

4

Description

Blood pressure

Timepoint

Before the intervention in first session and in final any sessions Before , after the intervention, 30 minutes after intervention, and after finish of the hemodialysis

Method of measurement

Checklist

5

Description

Respiratory rate

Timepoint

Before the intervention in first session and in final any sessions Before , after the intervention, 30 minutes after intervention, and after finish of the hemodialysis

Method of measurement

Checklist

6

Description

Pulse rate

Timepoint

Before the intervention in first session and in final any

sessions Before , after the intervention, 30 minutes after intervention, and after finish of the hemodialysis

Method of measurement

Checklist

7**Description**

Oxygen saturation

Timepoint

Before the intervention in first session and in final any sessions Before , after the intervention, 30 minutes after intervention, and after finish of the hemodialysis

Method of measurement

pulse oximeter

8**Description**

Mean blood pressure

Timepoint

Before the intervention in first session and in final any sessions Before , after the intervention, 30 minutes after intervention, and after finish of the hemodialysis

Method of measurement

Checklist

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The researcher is sitting on the chair beside the patients. The patients will hearing to guided imagery CD for 20 minutes. Researcher is filling the scales consists: anxiety and depression scale (HADS), Brief Fatigue Inventory , and hemodynamic parameters before intervention, after intervention, 30 minutes after intervention and end of hemodialysis.

Category

Other

2**Description**

Interference will not occur in the control group

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Martyr Rajai Hospital

Full name of responsible person

Yaser Beyzaie

Street address**City**

Karaj

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahed University Vice chancellor for research

Full name of responsible person

Dr. Zahra Kiasalari

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahed University Vice chancellor for research

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**

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

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

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way Tehran .

City

Tehran

Postal code**Phone**

+98 21 5121 3071

Fax**Email**

nrejeh@yahoo.com

Web page address**Person responsible for scientific**

inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

Other areas of specialty/work

Street address

Shahed University, Opposite to Holy Shrine of Imam
Khomeini, Tehran-Qom Express way Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 5121 3071

Fax

Email

nrejeh@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

Other areas of specialty/work

Street address

Shahed University, Opposite to Holy Shrine of Imam
Khomeini, Tehran-Qom Express way Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 5121 3071

Fax

Email

nrejeh@yahoo.com

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