

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The Effect of Music on Depression and Anxiety in Patients Receiving Dialysis in Beheshti Hospital, in Hamedan city, Iran in 2016

#### Protocol summary

Decrease Anxiety; Decrease depression

#### Study aim

The main purpose is determining the effect of music on depression and anxiety in hemodialysis patients referring to Hamedan health centers in 2016

#### Design

This study is a single-blind, control clinical trial. The samples were selected from patients by available sampling method. Patients who had hemodialysis on even days were in the experimental group and patients who had hemodialysis on odd days were in control group and the total number of samples was 50.

#### Settings and conduct

This study is conducted on hemodialysis patients referring to Hamedan health centers. For the patients in the intervention group, speechless music is played. Before and after the intervention, the level of anxiety and depression of the subjects is measured by a research collaborator who does not know about the patient's placement in the test and control group.

#### Participants/Inclusion and exclusion criteria

Entry requirements: being alert; having an active file in the dialysis center; age from 30 to 65 years old; ability to read and write; gain score 30 and above Spielbergers Anxiety Measurement Questionnaire; history of at least three years of dialysis. Exit criteria: hearing problem; unwillingness to participate in the study; taking sedative and anti-anxiety medication; incident or bad experience during the last six months; kidney transplantation or use of peritoneal dialysis methods; drug addiction; psychological problems. History of thyroid gland diseases and the use of drugs that affect it Pregnancy

#### Intervention groups

For the patients in the experimental group, music is played by headphones for 20 minutes at the start of dialysis. Before and after the intervention, variables are measured. For the control group, routine actions are performed and variables are measured before dialysis and after dialysis.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170619034641N3**

Registration date: **2018-06-13, 1397/03/23**

Registration timing: **prospective**

Last update: **2018-06-13, 1397/03/23**

Update count: **0**

##### Registration date

2018-06-13, 1397/03/23

##### Registrant information

##### Name

Alireza Abdi

##### Name of organization / entity

nursing and midwifery school, Kermanshah university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3725 0111

##### Email address

arabdi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-05, 1397/04/14

##### Expected recruitment end date

2018-11-20, 1397/08/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The Effect of Music on Depression and Anxiety in Patients Receiving Dialysis in Beheshti Hospital, in Hamedan city, Iran in 2016

**Public title**  
The Effect of Music on Depression and Anxiety in Patients Receiving Dialysis

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Being alert Having an active file in the dialysis center  
Age from 30 to 65 years old Ability to read and write  
Hemodynamic stability Gain score 30 and above  
Spielbergers Anxiety Measurement Questionnaire History of at least three years of dialysis  
**Exclusion criteria:**  
Hearing problem Unwillingness to participate in the study  
Any illness or severe disability (other than diabetes and high blood pressure) Age under 30 and over 65 years  
Taking sedative and anti-anxiety medication Incident or bad experience during the last six months Kidney transplantation or use of peritoneal dialysis methods  
Drug Addiction History of epilepsy Psychological problem  
History of thyroid gland diseases and the use of drugs that affect it Pregnancy The habit of listening to music It was unwilling and unwilling to listen to music Patient death

**Age**  
From **30 years** old to **65 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The sample was selected from patients by available sampling method and the patients were randomly assigned into two groups of control and intervention (no verbal music). Patients who had Hemodialysis in even days were in the intervention group and patients who had hemodialysis on odd days were in the control group.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
A research fellow that responsible for measuring the variables of depression and anxiety was waiting outside the room for hemodialysis. He did not know the group in which the patients were located. He then entered the room and measured and recorded the rate of depression and anxiety

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics Committee of Kermanshah University of Medical Sciences  
**Street address**  
Shaheed Beheshti Hospital, Mahdiah Street, Ghaem Square  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
6541675517

**Approval date**  
2018-05-08, 1397/02/18

**Ethics committee reference number**  
ir.kums.rec.1397.032

## Health conditions studied

**1**

**Description of health condition studied**  
Chronic renal failure

**ICD-10 code**  
N18.5

**ICD-10 code description**  
Chronic kidney disease, stage 5

## Primary outcomes

**1**

**Description**  
Depression Score in the Beck Questionnaire

**Timepoint**  
Measuring depression before intervention and after the completion of dialysis

**Method of measurement**  
Beck Depression Questionnaire

**2**

**Description**  
Anxiety Scale in the Spielberger Questionnaire

**Timepoint**  
Measuring anxiety before intervention and after the completion of dialysis

## Method of measurement

Spillberger's Anxiety Questionnaire

## Secondary outcomes

### 1

#### Description

Anxiety Score

#### Timepoint

Before the intervention and after dialysis

#### Method of measurement

Spillberger's Anxiety Inventory

## Intervention groups

### 1

#### Description

Intervention group: the duration of the intervention period for the test group is 4 weeks, and each week for three days, each day for 20 minutes, music is played to the patient by headphones. Variables are measured and recorded each time before and after dialysis.

#### Category

Lifestyle

### 2

#### Description

Control group: patients in the control group receive the usual measures of the department, and variables are measured before dialysis and after dialysis

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital

##### Full name of responsible person

Mohamad Imani

##### Street address

Shaheed Beheshti Hospital, Mahdiah Street, Ghaem Square

##### City

Hamedan

##### Province

Hamadan

##### Postal code

6541675517

##### Phone

+98 81 1254 3265

##### Fax

##### Email

fmomenfar@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Behrooz Hamzeh

##### Street address

Vice Chancellor for Research, Kermanshah University of Medical Sciences, Shahid Beheshti Blv., Kermanshah, Iran

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##### Province

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#### Grant name

Vice Chancellor for Research, Kermanshah University of Medical Sciences

#### Grant code / Reference number

معاونت تحقیقات و فناوری دانشگاه علوم پزشکی کرمانشاه

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kermanshah University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Parvin Abasi

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

Kermanshah University of Medical Sciences, Shariati St., Kuy Dolat Abad

##### City

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
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Parvin Abasi  
**Position**  
Assistant Professor  
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## Person responsible for updating data

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P-abasi2003@kums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

if the desired journal or research deputy will request the data, the file will be in their disposal.

### When the data will become available and for how long

after two years from data collection

### To whom data/document is available

research deputy of KUMS, and editor in chief of the raised journal

### Under which criteria data/document could be used

to publish the paper and offering the final report of the project

### From where data/document is obtainable

contact to corresponding author

### What processes are involved for a request to access data/document

request via email

### Comments