# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

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

## Protocol summary

**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 conductedon 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**

Decrease Anxiety; Decrease depression

## 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 Recieving Dialysis in Beheshti Hospital, in Hamedan city, Iran in 2016

**Public title**

The Effect of Music on Depression and Anxiety in Patients Recieving 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 odds day 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, Mahdieh 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, Mahdieh 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 Beheshty Blv., Kermanshah, Iran
**City**
Kermanshah
**Province**
Kermanshah
**Postal code**
00988338279394
**Phone**
+98 83 3835 8258
**Email**
arabdi@kums.ac.ir
**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**

Kermanshah
**Province**
Kermanshah
**Postal code**
00988338279394
**Phone**
+98 83 3427 6489
**Email**
P-abasi2003@kums.ac.ir

## Person responsible for scientific 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**
Kermanshah
**Province**
Kermanshah
**Postal code**
00988338279394
**Phone**
+98 83 3427 6489
**Email**
P-abasi2003@kums.ac.ir

## Person responsible for updating data

**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**
Kermanshah
**Province**
Kermanshah
**Postal code**
00988338279394
**Phone**
+98 83 3427 6489
**Email**
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**