

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of music therapy on comfort rate and some vital signs of patients undergoing hemodialysis

Protocol summary

Summary

Objectives: The present study will intend to determine the effect of music therapy on the amount of comfort and some hemodynamic parameters of patients undergoing hemodialysis. Design: Clinical trial. Setting and conduct: 74 people will select from the hemodialysis patients in Hajar and Besat Hospitals, who will select by accessible method and based on the days (even or odd days). 37 people will allocate to the test group and 37 to the control group. Major Inclusion criteria: The patient has been undergoing hemodialysis for more than six months; Do not have a known history of psychiatric diseases; Do not suffer from hearing impairments which prevents using headphones. Major Exclusion criteria: Unstable hemodynamic status; Acute pain in other parts of the body; Developing cardiac and pulmonary disorders. Interventions: A pre-test will conduct before hemodialysis using a comfort questionnaire in both the test group and control group and the vital signs will record. Music will play only for the test group during hemodialysis in three sessions, and no special action will take on the control group. After each hemodialysis session the vital signs will record, and the post-test will conduct. Main outcome: Comfort; Blood pressure; Heart rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092323446N8**
Registration date: **2016-10-23, 1395/08/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-23, 1395/08/02

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Aja University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of music therapy on comfort rate and some vital signs of patients undergoing hemodialysis

Public title

The effect of music on comfort and vital signs of hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The patient is willing to enter the study; Does not use narcotics (as it interferes with and adversely affects the result of the study in respect of the

pain); More than six months has elapsed since the hemodialysis was started, and it is stable; Undergoes hemodialysis only three times a week; Does not attend as a guest from other centers; Is able to understand Farsi; Does not have a known history of psychiatric diseases; Likes music; Does not use another music during the intervention; Is between 30 to 85 years of age; Does not suffer from hearing impairments which prevents using headphones. Exclusion criteria: Unstable hemodynamic status; Acute pain in other parts of the body; Developing cardiac and pulmonary disorders; The patient's unwillingness to hear music.

Age

From **30 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Aja University of Medical Sciences

Street address

AJA University of Medical Sciences, Etemadzadeh St, Fatemi St, Tehran

City

Tehran

Postal code**Approval date**

2016-02-15, 1394/11/26

Ethics committee reference number

IR.AJAUMS.REC.1394.44

Health conditions studied**1****Description of health condition studied**

Chronic Renal Failure

ICD-10 code

N18.5

ICD-10 code description

End stage kidney disease on dialysis

Primary outcomes**1****Description**

Comfort

Timepoint

Before intervention, After the first session, After the second session, After the third session.

Method of measurement

General Comfort Questionnaire Colcaba

2**Description**

Blood pressure

Timepoint

Before intervention, After the first session, After the second session, After the third session.

Method of measurement

Use of stethoscope and manometer

3**Description**

Heart rate

Timepoint

Before intervention, After the first session, After the second session, After the third session.

Method of measurement

Use of chronometer

Secondary outcomes

empty

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

Test group: The blood pressure and heart rate will record before the hemodialysis; followed by 30 minutes music therapy during the hemodialysis in three sessions; the blood pressure and heart rate will record again after the hemodialysis session.

Category

Other

2**Description**

Control group: The blood pressure and heart rate will record before the hemodialysis; no intervention will

make during the hemodialysis in three sessions; the blood pressure and heart rate will record again after the hemodialysis session.

Category

Other

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

Hajar Hospital

Full name of responsible person

Mojtaba Zarurati

Street address**City**

Tehran

2**Recruitment center****Name of recruitment center**

Besat Nahaja General Hospital

Full name of responsible person

Mojtaba Zarurati

Street address**City**

Tehran

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

Vice chancellor for research of AJA University of Medical Sciences

Full name of responsible person

Dr. Kamran Azma

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AJA University of Medical Sciences, Etemadzadeh St., Fatemi St, Tehran

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Tehran

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 of AJA 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**

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Full name of responsible person

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Position

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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