

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The Effect of Holy Qur'an Recitation on the inflammatory factors in Hemodialysis Patients

Protocol summary

Study aim

Effect of the Holy Qur'an Recitation on the inflammatory factors in hemodialysis patients

Design

Controlled randomized clinical trial, with parallel groups, without blindness.

Settings and conduct

This is a randomized controlled clinical trial study in which two groups of intervention (receiving holy qur'an recitation) and control (silent mode) will be done on 50 hemodialysis patients referring to Kowsar hospital affiliated to Semnan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to listen to the Holly Quran; at least six months of treatment with hemodialysis; having hemodynamic stability; no history of recent infection (recent 3 months); obtain Score 10 for the anxiety and 7 for the depression items of the Hospital Anxiety and Depression Scale. Exclusion criteria: Hearing impairment; left handed; reciter of quran; Arabic speaking patients

Intervention groups

Intervention group: Patients who receive the Quran voice (Yasin Surah) for a month, three times per week for 20 minutes (immediately after connecting the patient to the dialysis machine and hemodynamic stability) via headphones. Control group: Patients who receive only headphones in silent mode (immediately after connecting the patient to the dialysis machine and hemodynamic stability) for one month, three times a week for 20 minutes.

Main outcome variables

Inflammatory factors (IL6, ESR, CRP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120109008665N9**

Registration date: **2019-11-04, 1398/08/13**

Registration timing: **prospective**

Last update: **2019-11-04, 1398/08/13**

Update count: **0**

Registration date

2019-11-04, 1398/08/13

Registrant information

Name

Hassan Babamohamadi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4190

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babamohamadi@sem-ums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Holy Qur'an Recitation on the inflammatory factors in Hemodialysis Patients

Public title

The Effect of Holy Qur'an Recitation on the inflammatory factors

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to listen to the Holly Quran Consent to participate in the study Age range 20 to 65 years At least six months of treatment with hemodialysis Consciousness having hemodynamic stability No history of recent infection (recent 3 months) The lack of serious psychiatric problems Obtain Score 10 for the anxiety and 7 for the depression items of the Hospital Anxiety and Depression Scale (HADS) No history of long-term use of corticosteroids and immunosuppressive drugs

Exclusion criteria:

left handed Hearing impairment Reciter of Quran Arabic speaking patients

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of samples to two groups (intervention or control) will be done randomly using random blocks method. 25 blocks with 2 cases in each are created and every time randomly a block will be selected. In this method, A: represent intervention group; B: control.

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 Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences (SEMUMS),
Vice Chancellor of Research and Technology , Bassij
Blvd., Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3519899951

Approval date

2019-09-17, 1398/06/26

Ethics committee reference number

IR.SEMUMS.REC.1398.154

Health conditions studied

1

Description of health condition studied

Chronic Kidney Disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Level of the inflammatory factor (IL6)

Timepoint

Before intervention and one month later

Method of measurement

Using an ELISA kit for measuring human IL-6, product of Diaclone France

2

Description

Level of the inflammatory factor (Erythrocyte Sedimentation Rate)

Timepoint

Before intervention and one month later

Method of measurement

ESR measurement using ESR tube containing sodium citrate solution, Product of Teb Shahr Company

3

Description

Level of the inflammatory factor (C Reactive Protein)

Timepoint

Before intervention and one month later

Method of measurement

CRP measurement, using ELISA, Using the XL Selectra device, a product from the Netherlands

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Music therapy intervention on the experimental group are done according to the prepared protocol based on similar studies. The aim of music therapy in this study is application of relaxing and mystical of Holy Quran, Yasin Surah with voice of Shateri Professor (Tartil), that is selected by consulting by a clergyman. This surah is playback 3 times in week, and 20 minutes every session (immediately after connecting the patient to the dialysis machine and hemodynamic stability) through mp3 player and a headphone within a month.

Category

Treatment - Other

2

Description

Control group: for control group, no specific intervention will be applied and they receive only routine cares along with the headphone in silent mode. This procedure is performed 3 times in week, and 20 minutes every session (immediately after connecting the patient to the dialysis machine and hemodynamic stability) through mp3 player and a headphone within a month.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital affiliated to Semnan University of Medical Sciences

Full name of responsible person

Hassan Babamohamadi

Street address

Kowsar Hospital; Amin Blv; Golestan town; Semnan

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Email

kowsarhospital@semums.ac.ir

Web page address

<http://kosarhos.semums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

Street address

Semnan University of Medical Sciences, Vice Chancellor of Research and Technology, Basidj Blv, Semnan, Iran

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rds@semums.ac.ir

Web page address

<http://rtvc.semums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Hassan Babamohamadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery Faculty, Semnan University of Medical Sciences, 5 Kilometers of Damghan Road, Semnan, Iran

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Position

Associate Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable