

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study of the effect of spiritual counseling on fear of death in hemodialysis patients

Protocol summary

Study aim

Determination of the effect of spiritual counseling on the fear of death in hemodialysis patients

Design

This study is a randomized, double-blind clinical trial with a control group in which 86 patients undergoing hemodialysis referring to Modarres Hospital in Saveh in 1398 will participate.

Settings and conduct

The present study will be conducted at the Dialysis Center of Modares Hospital in Saveh on hemodialysis patients. The outcome evaluator and the statistical analyzer will not know how to place the samples in the intervention and control groups. Also, spiritual counseling will be done individually twice a week, including 6 sessions in the morning or evening.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing hemodialysis for at least 3 months Patients undergoing hemodialysis regularly 3 times a week Age between 18 to 65 years' old The desire to participate in the study Having the ability to attend meetings exclusion criteria: the lack of full awareness of time, place, and individuals

Intervention groups

In the intervention group, in addition to the usual treatments, spiritual counseling will be done individually twice a week, including six sessions in the morning or evening shift in the hemodialysis department. Each session lasts between 20 and 45 minutes. Spiritual counseling approach in this research will be based on spiritual interventions and religious beliefs. It also includes Spiritual imagination, Benson's progressive muscle relaxation, hearing music using educational CD, reading the Qur'an, doing forgiveness exercises, and more. The control group will receive only the usual treatment during this period.

Main outcome variables

Fear of Death

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161210031328N10**

Registration date: **2019-05-09, 1398/02/19**

Registration timing: **prospective**

Last update: **2019-05-09, 1398/02/19**

Update count: **0**

Registration date

2019-05-09, 1398/02/19

Registrant information

Name

Mahbobeh Sajadi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3402 0115

Email address

m.sajadi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studt of the effect of spiritual counseling on fear of death in hemodialysis patients

Public title

The effect of spiritual counseling on fear of death in hemodialysis patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing hemodialysis for at least 3 months
Patients undergoing hemodialysis regularly 3 times a week
Age between 18 to 65 years old
The desire to participate in the study
Having the ability to attend meetings

Exclusion criteria:

Unwillingness to participate in the study
Lack of full awareness of time, place and individuals

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are divided into intervention and control groups using randomized block allocation method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Individuals with inclusion criteria are divided into intervention and control groups according to the random numbers table. One of the groups is A and the other is called B. Before and after the intervention, the information is collected by the evaluator of the outcome that is unaware of the Classification of the groups. Data analysis is also done by someone who is unaware of the allocation of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Alam al hoda St, Rail road St

City

Arak

Province

Markazi

Postal code

3814957558

Approval date

2019-01-22, 1397/11/02

Ethics committee reference number

IR.ARAKMU.REC.1397.294

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

Dialysis

ICD-10 code

Y84.1

ICD-10 code description

Kidney dialysis

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

Fear of death

Timepoint

At the beginning of the study and six weeks later

Method of measurement

The Collett-Lester fear of death scale

Secondary outcomes

empty

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

Intervention group: In the intervention group, in addition to the usual treatments, spiritual counseling will be done individually twice a week, including six sessions in the morning or evening shift in the hemodialysis department. Each session lasts between 20 and 45 minutes. Spiritual counseling approach in this research will be based on spiritual interventions and religious beliefs. It also includes Spiritual imagination, Benson's progressive muscle relaxation, hearing music using educational CD, reading the Qur'an, doing forgiveness exercises, and more.

Category

N/A

2

Description

Control group: The control group will not receive intervention from the research team during this period.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modares Hospital

Full name of responsible person

Mahbobeh Sajadi

Street address

Shahid Modares Hospital, Modares Sq.

City

Saveh

Province

Markazi

Postal code

3915953983

Phone

+98 86 4222 3026

Email

info@savehums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

Street address

Arak University of Medical Sciences, Basij Sq.,
Sardasht Region

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Province

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3819693345

Phone

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info@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Latest degree

Ph.D.

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Email

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data, such as information on the main outcome and the demographic information, can be shared.

When the data will become available and for how long

2 years after publishing of results.

To whom data/document is available

Researchers in academic and scientific institutions.

Under which criteria data/document could be used

In order to utilize scientific purposes and mention the source used

From where data/document is obtainable

Dr. Mahbobeh Sajadi E-mail address:
sajadimahbobeh@yahoo.com

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

After receiving the email, the information will be sent within 4 to 5 working days.

Comments