

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of self-care training on death anxiety in patients referred to the hemodialysis unit of Ali Ebn Abitaleb Hospital in Rafsanjan, 2023

Protocol summary

Study aim

If the positive effect of self-care on reducing the death anxiety of hemodialysis patients is observed, the results of this research can be used as a cost-effective solution without side effects and accessible and easy for patients, caregivers and therapists of hemodialysis patients.

Design

A clinical trial with a control group, with parallel groups, without blinding, randomized, on 50 patients was used for randomization using the random minimization method.

Settings and conduct

The place of study is in dialysis department of Ali Ibn Abitalib Hospital in Rafsanjan city. The intervention group received self-care training in three sessions and no intervention will be done in the control group.

Participants/Inclusion and exclusion criteria

Consent to participate in the study; Age above 18 years; Suffering from end-stage chronic kidney disease confirmed by a specialist doctor; Knowledge of disease diagnosis and prognosis; Alert and aware of place and time; Receive at least two dialysis sessions per week; A history of at least six months of hemodialysis; Not having known mental illness and cognitive problems to learn self-care; Not having a history of the death of loved ones in the last few months; Physical ability to do personal work.

Intervention groups

Intervention group: self-care training on death anxiety.
Control group: no intervention will be implemented.

Main outcome variables

Death anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230610058437N1**

Registration date: **2023-08-28, 1402/06/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-28, 1402/06/06**

Update count: **0**

Registration date

2023-08-28, 1402/06/06

Registrant information

Name

hananeh abbaszadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-16, 1402/05/25

Expected recruitment end date

2023-09-16, 1402/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of self-care training on death anxiety in patients referred to the hemodialysis unit of

Public title

Investigating the effect of self-care training on death anxiety in patients referred to the hemodialysis unit of Ali Ebn Abitaleb Hospital in Rafsanjan, 2023

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years Suffering from end-stage chronic kidney disease confirmed by a specialist doctor Knowledge of disease diagnosis and prognosis Alert and aware of place and time Receive at least two dialysis sessions per week A history of at least six months of hemodialysis Not having known mental illness and cognitive problems to learn self-care Not having a history of death of loved ones in the last few months Physical ability to do personal work

Exclusion criteria:

Having lethargy and weakness or reduced level of consciousness Hospitalization Unwillingness to participate in the study The existence of psychological problems

Age

From **18 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

First, purposeful sampling based on the criteria for entering the study and qualified people in two control and intervention groups using random minimization based on the categories of death anxiety scores in the table below (in three categories, low death anxiety with a score of 0-6, moderate death anxiety with a score of 7-9 and severe death anxiety with a score of 10-15) will be assigned. The entry of the first sample in each floor is a simple random draw will be made and the next samples will be based on the total number of samples in each floor and each group.

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 Rafsanjan University of Medical Sciences

Street address

Rafsanjan - Imam Ali Boulevard - Central Organization

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2023-05-03, 1402/02/13

Ethics committee reference number

IR.RUMS.REC.1402.016

Health conditions studied

1

Description of health condition studied

Death anxiety in hemodialysis patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The level of death anxiety

Timepoint

The measurement of death anxiety score will be before the start of the intervention and 4 weeks after the start of the self-care training intervention.

Method of measurement

Death anxiety score is measured using Templer's 15-question questionnaire in hemodialysis patients.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group together with a family member (the one who has the most role in patient care) in three sessions for two weeks, (two sessions in the first week and one session in the second week) for 30-45 minutes of training how to They will receive individual self-care and question and answer. During training, the control group will be separated from the intervention group and will be placed at a certain distance away from the test group. In the first session of

training about the recognition of chronic kidney failure, its symptoms and complications, psychological changes in these patients, including anxiety, stress, depression and death anxiety and treatment follow-up, drugs and finally the importance of self-care in hemodialysis patients and in the second session Adherence to diet and weight control and liquid consumption, exercise and activity, sleep and rest, daily weighing and skin care (fistula) will be taught.

Category

Other

2**Description**

Control group: no intervention will be implemented in the control group.

Category

Other

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

Dialysis Department of Ali Ibn Abitalib Hospital

Full name of responsible person

Hananneh Abbaszadeh

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Taleghani Boulevard, Ayatollah Saidi Square, Hazrat Ali Ibn Abi Talib Hospital

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

Rafsanjan University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Rafsanjan 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**

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Tayebbeh Negahban Bonabi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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