

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of the spiritual care on life expectancy and death anxiety in patients with end-stage chronic kidney disease under hemodialysis

Protocol summary

Summary

Goal: effects of spiritual care on life expectancy and death anxiety of patients undergoing hemodialysis with end-stage chronic renal failure in the case and control group
Design of the study: Randomized Population of the study: Patients undergoing hemodialysis with end-stage chronic renal failure
Sample size: Sixty patients
Interventions: Effects of spiritual care on life expectancy and death anxiety
Blinding: Not blinded
Trial phase: 2-3
Study Design: Interventional
One central Primary outcome measure: Life expectancy and Death anxiety
Inclusion criteria of the study: 1. end-stage chronic renal failure confirmed by the physician, 2. knowing the diagnosis and prognosis of their disease. Exclusion criteria of the study: 1. incidence of any stressful event for patients once the study has begun, 2. unwillingness to continue the study for any reason.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030826961N1**

Registration date: **2016-05-22, 1395/03/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-22, 1395/03/02

Registrant information

Name

Shila Amini

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 988138380320

Email address

sh.amini@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Government sources

Expected recruitment start date

2016-07-05, 1395/04/15

Expected recruitment end date

2016-08-05, 1395/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the spiritual care on life expectancy and death anxiety in patients with end-stage chronic kidney disease under hemodialysis

Public title

The Effect of Spiritual Care on Life Expectancy and Death Anxiety in Hemodialysis patients.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria of the study: 1. end-stage chronic renal failure confirmed by the physician, 2. knowing the diagnosis and prognosis of their disease, 3. hemodialysis at least for 6 months, 4. having physical and mental capability of answering the questions, 5. not knowing the mental disorders diagnosed by the physician, and 6. having minimum ability of reading and writing. Exclusion criteria of the study: 1. incidence of any stressful event for patients once the study has begun, 2. unwillingness to continue the study for any reason, and 3.

hospitalization because of the disease relapse.

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomized: permutation block

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Beginning of Ayatollah Kashani Blvd, Khajeh Rashid Crossroads.

City

Hamadan

Postal code

Approval date

2016-03-03, 1394/12/13

Ethics committee reference number

IR.UMSHA.REC.1394.528

Health conditions studied

1

Description of health condition studied

End stage kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Death Anxiety

Timepoint

Before and one month after the start of the study

Method of measurement

Templer Death Anxiety Questionnaire

2

Description

Life Expectancy

Timepoint

Before and one month after the start of the study

Method of measurement

Life Expectancy Schneider Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The case group: (1): The case group will receive spiritual care besides the routine treatments. The patients in the case and control group will complete a demographic information questionnaire before the intervention. The patients in the case and control group will also complete the Templer's death anxiety scale and Schneider's life expectancy scale before and after the intervention. Mean score of death anxiety and life expectancy of the two groups before and after the intervention will be eventually presented and compared. Prior to implementation of the spiritual care program, library resources and articles will be reviewed to prepare a care training package (booklets and CDs) for hemodialysis patients in the case group. The spiritual care program in this study will be held in four one-hour sessions individually twice a week in the morning or evening shift at bedside in the hemodialysis ward. The spiritual care model in the case group will include the following items: A- supportive presence involving the following items: 1. developing trust, empathy, and honesty between nurses and patients to establish a good relationship during sessions, 2. carefully listening to the patients' words, concerns, and fears, 3. supporting the patients spiritually and mentally, 4. enhancing patients' hope and inner forces, 5. uttering positive sentences and reinforcing sound constructive thoughts, 6. communicating with patients verbally and non-verbally, 7. answering patients' questions, explaining the course of treatment to the patients, and providing them with information on their disease in order to diminish their physical and mental stresses, and 8. encouraging the patients to use recreational places, B- support patients' rituals: 1. helping the patients to find meaning of their life and the fact that no event is out of the divine providence, 2. providing necessary facilities for doing religious practices (including a turbah and a prayer rug and recommending

patients' family to help the patients in saying prayers), 3. encouraging the patients to say prayers and read Quran, 4. encouraging the patients to express their religious beliefs, and 5. encouraging the patients to talk with clergymen, and C- use of supportive systems: 1. encouraging the patients to communicate with people with whom they feel comfortable, 2. supporting the patients emotionally on the part of patients' family and medical team such that the patients feel valued, including loving, accepting, and respecting them, 3. recommending patients' family to help the patients do their daily activities, such as household chores, and 4. encouraging the patients to go to work. It should be noted that the first session involve principles on the supportive presence. The support for patients' rituals will be emphasized in the second session. The third session will be dedicated to patients' use of specific supportive systems. The materials taught in the first three sessions will be concluded in the fourth session, and the patients will be requested to express their views and questions about the spiritual care provided for them. It will be tried to obviate any ambiguity that may arise about the training materials.

Category
Lifestyle

2

Description

The control group (Group 2): This group will receive the routine medical and nursing care. Contains Hemodynamic monitoring During Hemodialysis. Correct hemodialysis and Control complications of hemodialysis.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Medical Educational Center
Full name of responsible person
Shila Amini
Street address
Beginning Eram Blvd.Ghaem Square
City
Hamadan

2

Recruitment center

Name of recruitment center
Beast Medical Eeducational Center
Full name of responsible person
Shila Amini
Street address
Shahid Beheshti Blvd
City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Hamadan University of Medical Sciences
Full name of responsible person
Dr. Khudayar Oshvandi
Street address
nursing of College-Opposite the People's Park
City
Hamadan

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 Hamadan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamadan University of Medical Science
Full name of responsible person
Khodayar Oshvandi
Position
Nursing PHD
Other areas of specialty/work
Street address
College of nursing-Opposite the People's Park
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Postal code
38698-65178
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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University of Medical Science

Full name of responsible person

Khodayar Oshvandi

Position

Nursing PHD

Other areas of specialty/work**Street address**

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Email

oshvandi@umsha.ac.ir

Web page address

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