Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of spiritual care based on Sound-Heart model on Pain, Fatigue and life expectancy of hemodialysis patients

Protocol summary

Study aim

Investigating the effect of spiritual care based on Sound-Heart model on pain, fatigue and life expectancy of hemodialysis patients referred to the hemodialysis center of Ostad Motahari Jahrom Hospital in 2024

Design

A clinical trial with a control group, parallel groups, and randomized block design was conducted on 68 patients. Randomization was carried out using the Random Allocation Software.There is no blindness in this study.

Settings and conduct

This study will be conducted at the Hemodialysis Center of Ostad Motahari Hospital in Jahrom. Each patient will receive six in-person sessions of spiritual care, with two sessions per week.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having a weekly hemodialysis schedule, having been on hemodialysis for at least one year, no history of previous kidney transplantation, aged between 18 and 80 years, Muslim, full awareness of time, place, and person, not deaf to ensure effective communication, physical and mental readiness to answer questions, and no history of mental illness or use of psychiatric medications. exclusion criteria :occurrence of a crisis event affecting the patient after the start of the research, the patient's unwillingness to continue participating in the study, hospitalization due to disease relapse or transplantation, and death of the patient during the course of the study.

Intervention groups

In the intervention group, spiritual care will be provided based on the Salim Heart Model. Patients will receive spiritual care in addition to their regular care and during dialysis. The spiritual care will be based on religious spirituality and will focus on improving four relationships of human beings: relationship with God, relationship with oneself, relationship with others, and relationship with the environment.Control group: will receive routine care

Main outcome variables

Pain, Fatigue and Life Expectancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240511061750N1**
Registration date: **2024-09-11, 1403/06/21**
Registration timing: **prospective**

Last update: **2024-09-11, 1403/06/21**
Update count: **0**

Registration date

2024-09-11, 1403/06/21

Registrant information

Name

zahra sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5422 5721

Email address

z.sadeghi@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-22, 1403/07/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of spiritual care based on Sound-Heart model on Pain, Fatigue and life expectancy of hemodialysis patients

Public title
Effect of Spiritual care based on Sound-Heart model on pain, fatigue and life expectancy of hemodialysis patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Having a hemodialysis schedule every week At least one year has passed since the patient started hemodialysis Without a previous history of kidney transplant Muslim Full awareness of time, place, and person Not being deaf in order to establish effective communication Physical and Mental Readiness of the Patient for Answering Questions No history of mental illness or use of psychiatric medications Possessing at least basic literacy skills and the ability to speak Persian

Exclusion criteria:
Occurrence of a crisis event affecting the patient after the research has begun The patient's unwillingness to continue participating in the study Hospitalization of the patient due to disease relapse Patient undergoing transplantation or death during the course of the study

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients undergoing hemodialysis will be included in the study using a convenience sampling method. Once the number of participants is determined, they will be allocated into intervention and control groups using block randomization. Specifically, 17 blocks of 4 will be used for this purpose, with random allocation managed through the Random Allocation Software version 2.

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 Jahrom University of Medical Sciences

Street address
Medical School,Pardis Campus, Motahari Boulevard

City
Jahrom

Province
Fars

Postal code
7414846199

Approval date
2024-07-13, 1403/04/23

Ethics committee reference number
IR.JUMS.REC.1403.013

Health conditions studied

1

Description of health condition studied
Hemodialysis patients

ICD-10 code
Z49

ICD-10 code description
Encounter for care involving renal dialysis

Primary outcomes

1

Description
Fatigue

Timepoint
Before the intervention , immediately after the intervention, and one month after the intervention.

Method of measurement
Multidimensional Fatigue Inventory (Mfi)

2

Description
Pain

Timepoint
Before the intervention , immediately after the intervention, and one month after the intervention

Method of measurement
Numeric Pain Rating Scale (Nprs)

Secondary outcomes

1

Description
Life Expectancy

Timepoint

Before the intervention , immediately after the intervention, and one month after the intervention

Method of measurement

Snyder Life Expectancy Questionnaire

Intervention groups

1

Description

Intervention Group: Spiritual care will be provided based on the Salim Heart Model. In addition to their usual care and during dialysis, patients will receive this spiritual care. The spiritual care will be based on religious spirituality and will focus on improving the four key relationships of the individual: relationship with God, relationship with oneself, relationship with others, and relationship with the environment. Each patient will receive six sessions of spiritual care (totaling 68 sessions), conducted twice a week on hemodialysis days, between 8 AM to 12 PM or 2 PM to 6 PM.

Category

Lifestyle

2

Description

Control group: will receive routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ostad Motahari Hospital Hemodialysis Center, Jahrom

Full name of responsible person

Zahra Sadeghi

Street address

Ostad Motahari Hospital, Ostad Motahari Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Dr. Amir Abdoli

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Zohre badiyepeyma jahromy

Position

Asistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing, Jahrom University of Medical Sciences, At the end of Shahid Motahari St., Jahrom, Fars, Iran.

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
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Other areas of specialty/work
Nursery

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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to the privacy of the subjects these items are not shared.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is 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
No - There is not a plan to make this available

Title and more details about the data/document
The data that are going to be available will be discussed in chapters four and five of the thesis and finally a brief explanation of them will be given in the article extracted from thesis.

When the data will become available and for how long
The access period starts 6 months after the results are published.

To whom data/document is available
access for researchers working in academic and scientific institutions.

Under which criteria data/document could be used
To publish articles and scientific references

From where data/document is obtainable
Jahrom University of Medical Sciences, Dr. Zohra Badiyepeyma Jahrom.

What processes are involved for a request to access data/document
In order to obtain the required data, dear researchers can send an email to Dr. Zohra Badiye Peyma at z.badiyepeyma@gmail.com, which will be answered within 14 days.

Comments