Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of spiritual care program versus control group on loneliness and depression in hemodialysis patients: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of spiritual care program versus control group on loneliness and depression in hemodialysis patient

Design
This is a non-blinded randomized clinical trial with a control group with parallel groups, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Beheshti Hospital in Hamadan city, involving 74 eligible hemodialysis patients. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 65, Undergoing hemodialysis treatment for at least 3 months, twice a week, Speaking Persian, Literacy, Shiite Muslim; Exclusion criteria: Neurological and mental problems

Intervention groups
Intervention group: Routine dialysis care plus spiritual care program sessions for 45 to 60 minutes daily for 6 sessions Control group: Routine dialysis care

Main outcome variables
Primary outcome: Mean loneliness score, mean depression score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N550**
Registration date: **2025-03-03, 1403/12/13**
Registration timing: **prospective**

Last update: **2025-03-03, 1403/12/13**
Update count: **0**

Registration date
2025-03-03, 1403/12/13

Registrant information

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Name of organization / entity
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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-04, 1404/01/15

Expected recruitment end date
2025-06-05, 1404/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of spiritual care program versus control group on loneliness and depression in hemodialysis patients: a randomized clinical trial

Public title
Effect of spiritual care program versus control group on loneliness and depression in hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 Undergoing hemodialysis treatment for at least 3 months, twice a week Speaking Persian Literacy Shiite Muslim

Exclusion criteria:

Neurological and mental problems

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave.

City

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Province

Hamadan

Postal code

6517838695

Approval date

2025-02-15, 1403/11/27

Ethics committee reference number

IR.UMSHA.REC.1403.831

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

Primary outcomes

1

Description

Mean loneliness score

Timepoint

Before intervention and at the end and one month after intervention

Method of measurement

Using the Russell Loneliness Scale (UCLA-LS)

2

Description

Mean depression score

Timepoint

Before intervention and at the end and one month after intervention

Method of measurement

Using the Beck Depression Inventory-Short Form (BDI-S)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine dialysis care plus spiritual care program sessions for 45 to 60 minutes daily for 6 sessions (including assessing patients' spiritual needs, religious care such as reciting the Quran, using relaxation techniques, explaining the concept of life and death, encouraging patients to seek help from their gods, strengthening mood-enhancing measures, strengthening positive thinking, increasing creativity in self-care and reducing dependency, establishing communication with health system staff, reducing anxiety, and increasing adaptability)

Category

Treatment - Other

2

Description
Control group:Routine dialysis care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital in Hamadan city
Full name of responsible person
Parisa Rostami
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Sponsors / Funding sources

1

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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
Hamedan 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
Hamedan University of Medical Sciences
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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