Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Spiritual Counseling based on Sound Heart Model on the Spiritual Well-being, Depression and Anxiety in Dialysis patients.

Protocol summary

Study aim
Increasing spiritual health, reducing stress and anxiety in hemodialysis patients

Design
The present study is a clinical trial study, before and after intervention. The aim of this study was to determine the effect of autonomous spiritual counseling based on the heart-healthy model on the dependent variable of spiritual well-being, depression and anxiety in hemodialysis patients.

Settings and conduct
The demographic data of patients will be studied and then they will be selected on the basis of inclusion criteria. Then, the patients will be informed of the method of study (Sound of heart model) in details. Then, written informed consent is taken from them. They are asked to fill 3 questionnaires, (Spiritual health, depression and anxiety).Patients will be divided into experimental and control groups by random allocation.Two groups are not interconnected together. After intervention, all three questionnaires must be filled again and compared to control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-adult patients (18 years or older) 2. The minimum reading and writing literacy 3- Being able to communicate to complete the questionnaire 4. No history of chronic mental illness in the past and now 5. Not to use psychosocial drugs, Farsi language, have at least one year of dialysis, dialysis at least twice a week. 6. Not having a history of attending spiritual meetings or spiritual training sessions simultaneously. Exclusion criteria: 1) Another other life-threatening diseases 2) No desire to continue the research on the patient's side

Intervention groups
The intervention group of hemodialysis patients who receive spiritual counseling.The control group of hemodialysis patients do not receive spiritual counseling.

Main outcome variables
Quality of Life mental health Spiritual care based on Selim's Heart Consultation Model

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181103041532N1**
Registration date: **2018-12-20, 1397/09/29**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-20, 1397/09/29**
Update count: **0**

Registration date
2018-12-20, 1397/09/29

Registrant information

Name
Zahra Nasrollahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3320 9074

Email address
znasrollahi2@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-06, 1397/08/15

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of Spiritual Counseling based on Sound Heart Model on the Spiritual Well-being, Depression and Anxiety in Dialysis patients.

Public title
Effect of spiritual counseling on spiritual well-being, depression and anxiety in hemodialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Adult patients (over 18 years old) At least the reading and writing skills Being able to communicate to complete the questionnaire Not having a history of chronic mental illness in the past and now Not to use psychosocial drugs, Farsi language, have at least one year of dialysis, dialysis at least twice a week. Not having a history of attending spiritual meetings or spiritual health training courses simultaneously

Exclusion criteria:
A severe physical or psychological crisis in addition to kidney failure Cause of other life-threatening diseases Unwillingness to continue research on the part of the patient Transmission for hemodialysis to the other center by the patient Candidate for renal transplantation

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients are divided into two groups. A control group that takes only Dialysis treatment. The other group is Dialysis treatment plus spiritual counseling. Both groups, the control group and the test group, should remain unaware of the other group, as the information shouldn't exchange between two groups.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qom University of Medical Sciences

Street address
Qom University of Medical Sciences opposite of yadegar-e- Imam Ghadir BLV Qom Iran

City
Qom

Province
Ghoum

Postal code
3713649373

Approval date
2018-09-11, 1397/06/20

Ethics committee reference number
طرح پژوهشی بررسی تاثیر مشاوره معنوی مبتنی بر مدل قلب سلیم برسلامت معنوی، افسردگی واضطراب بیماران همودیالیزی شهر قم ۸۳ IR.MUQ.REC.1397.083 ۱۳۹۷/۶/۲۰

Health conditions studied

1

Description of health condition studied
dialysis

ICD-10 code
Z99.2

ICD-10 code description
Dependence on renal dialysis

Primary outcomes

1

Description
Spiritual well-being.

Timepoint
After intervention (after 10 consultation sessions).

Method of measurement
Questionnaire of Spiritual well-being.

2

Description
Anxiety.

Timepoint
After intervention (after 10 consultation sessions)

Method of measurement
Questionnaire of Anxiety.

3

Description
Stress.

Timepoint
After intervention (after 10 consultation sessions)

Method of measurement

Questionnaire of Stress

Secondary outcomes

1

Description
Stress score
Timepoint
Once upon a spiritual intervention
Method of measurement
Spiritual Health Questionnaire, Stress Questionnaire, Anxiety Inventory

2

Description
Anxiety Score
Timepoint
After spiritual intervention
Method of measurement
Through the questionnaire

Intervention groups

1

Description
There are two groups. 1. A control group that receives only conventional Dialysis treatments. 2. An intervention group that also undergoes a spiritual intervention in addition to Dialysis treatments. The spiritual intervention in 10 sessions is as the following: First session: Familiarity; second session: People's feelings and attitudes to life stress; Third session: Attention to the positive aspects of the problem and the purpose of life; Fourth session: The concept of health and its dimensions, spiritual well-being and the characteristics of the healthy human being; the Fifth session: The effect of different dimensions of health on each other; the sixth session: Self-awareness of self-care needs; the Seventh session; The development of social communication; the Eighth session; Coping with spiritual care recipes; meeting ninth: Self-control; Teaching the skill of self-assessment daily; Session 10: Completing questionnaires and answering questions and Final assessing.
Category
Behavior

2

Description
Intervention group: Spiritual counseling is based on the ŚALIM heart model on the hemodialysis patient intervention group, while hemodialysis treatment is also performed.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
zahra nasrollahi
Street address
qom medical university opposite of yadegar-e- Imam Ghadir BLV Qom Iran
City
Qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3320 9074
Email
znasrollahi2@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Dr. hossein saghafi
Street address
ghadir BLV Qom
City
qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3285 4011
Email
dr.hosseinsaghafi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum University of Medical Sciences

Full name of responsible person
zahra nasrollahi

Position
Assistant Prof.

Latest degree
Ph.D.

Other areas of specialty/work
Mycology

Street address
ghadir BLV qom

City
qom

Province
Ghoum

Postal code
3713649373

Phone
+98 25 3320 9074

Email
znasrollahi2@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
zahra nasrollahi

Position
assistant Prof.

Latest degree
Ph.D.

Other areas of specialty/work
Mycology

Street address
ghadir BLV Qom

City
qom

Province
Ghoum

Postal code
3713649373

Phone
+98 25 3320 9074

Email
znasrollahi2@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
zahra nasrollahi

Position
assistant prof.

Latest degree
Ph.D.

Other areas of specialty/work
Mycology

Street address
ghadir BLV Qom

City
Qom

Province
Ghoum

Postal code
3713649373

Phone
+98 25 3320 9074

Email
znasrollahi2@gmail.com

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
Not defined in the scheme. No need to feel

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