Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of spiritual care on the Quality of life and spiritual health in hemodialysis patients

Protocol summary

Summary

Aims:This study, aims to determine the effect of “Sound Heath spiritual care Consulting model” (as independent variable) on the quality of life and spiritual health in hemodialysis patients(the dependent variable) Methods: This is a controlled clinical trial study, before and after the intervention. The sample size in each of the two intervention and control groups, based on the following formula, was calculated 45 samples. Sample are selected according to inclusion Criteria from patients admitted to dialysis centers Baqiyatallah and Chamran Hospital. After explaining the method and obtaining informed consent, patients will be divided in two groups with Random allocation.Both of the control and test groups will complete SF KDQOL, daily spiritual experiences and spiritual health Ellison Palvtzyn questionnaires before the intervention .The control group will be trained by “Sound Heath spiritual health care consulting”.Then, three months after completion of the intervention, patients in both groups, will complete questionnaires. Finally the results obtained will be compared with statistical tests. Spiritual consulting sessions, including the following - First meeting: Greeting, orientation and Introduction - Second Session: Review of the patients’ feelings and attitudes to disease -Third session: Considering to the positive aspects of disease, Create optimism, the hope in the patient - Fourth Session: Create spiritual awareness - Fifth Session: Encourage patients to develop Social Communication, Training enjoying nature -Sixth Session: motivation to modify according to the patient's values and trusting in God - Seventh Session: Training in how to solve the problem and learning how to achieve emotional compatibility with problems. -Eighth Session: Self-control after intention Inclusion criteria:Being able to communicate to complete the questionnaire. Without history of chronic mental illness in the past and now. Persian Language Exclusion criteria:Withdrawing from continuing partnership .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120431233N1**
Registration date: **2017-02-09, 1395/11/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-09, 1395/11/21

Registrant information

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HALIMEH AKBARPOURMAZANDARANI
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences and the Center for Medicine and Religion

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of spiritual care on the Quality of life and spiritual health in hemodialysis patients

Public title
Pastoral care impact on quality of life and spiritual health for dialysis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: adult patients (over 18 years)؛ Being able to communicate to complete the questionnaire؛ no history of chronic mental illness in the past and now ؛ Not taking psychotropic drugs؛ Persian Language؛ at least 6 months of dialysis Exclusion criteria:Not wanting to continue research by the patients during the study ؛Transfer to hemodialysis patient during the study ؛ Kidney transplant during the study
Age
From **18 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
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's Baqiyatallah University of Medical Sciences
Street address
SHEYKHBAHAEE ALLEY-MULLASADRA STREET
City
TEHRAN
Postal code
Approval date
2016-12-13, 1395/09/23
Ethics committee reference number
IR.Bmsu.REC.13950180

Health conditions studied

1

Description of health condition studied
hemodialysis
ICD-10 code
N17-N19
ICD-10 code description
نارسایی مزمن کلیه

Primary outcomes

1

Description
Quality of Life
Timepoint
before and after and three months of training
Method of measurement
Quality of Life Questionnaire KDQOL-SF

2

Description
Spiritual Health
Timepoint
Before and after and three months of training
Method of measurement
Ellison and Palvtzyn spiritual health questionnaires

Secondary outcomes

1

Description
Daily Spiritual Experience
Timepoint
Before and after and three months of training
Method of measurement
Daily Spiritual Experience questionnaire

Intervention groups

1

Description
Training spiritual care model GHALBE SALIM during 8 training sessions or any time during dialysis is done with the consent of the patient and each session lasts about 45 minutes.
Category
Other

2

Description
In the control group only three sets of questionnaires at baseline, 2 and 5 months later and the controls are not being taught
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Minoo Asadzandi
Street address
Shahid Hemmat highway-Sheikh Bahaee street-Nosrati alley
City
Tehran

2

Recruitment center
Name of recruitment center
Chamran Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Medicine and Religionof Center
Full name of responsible person
Meddi mesri doctor
Street address
Baqiyatallah University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Medicine and Religionof Center
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
Name of organization / entity
Baqiyatallah University of Medical Sciences
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Minoo Asadzandi
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Person responsible for updating data

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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