

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 Health 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 Health 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

Name

HALIMEH AKBARPOURMAZANDARANI

Name of organization / entity

University Baqiyatallah

Country

Iran (Islamic Republic of)

Phone

+98 21 6651 4847

Email address

stu.haliakbar916@bmsu.ac.ir

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

SHEYKHBAAHEE 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

Full name of responsible person

Minoo Asadzandi

Position

PhD Research in Medical Sciences

Other areas of specialty/work

Street address

Shahid Hemmat highway-Sheikh Bahaee street-
Nosrati alley

City

tehran

Postal code

1456856451

Phone

+98 21 2264 8520

Fax

Email

zandi498@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Minoo Asadzandi

Position

PhD Research in Medical Sciences

Other areas of specialty/work

Street address

Number10-zolfaghari alley-shadman street-satarkhan
avenue

City

Tehran

Postal code

1456856451

Phone

+98 21 2264 8520

Fax

Email

zandi498@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Minoo Asanzandi

Position

PhD Research in Medical Sciences

Other areas of specialty/work

Street address

Shahid Hemmat highway-Sheikh Bahaee street-
Nosrati alley

City

Tehran

Postal code

1941736534

Phone

+98 21 2264 8520

Fax

Email

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