Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of education based on spiritual insight and action to Hemodialysis patients on their quality of life.

Protocol summary

Study aim

Determining the effect of education based on insight and spiritual action on Hemodialysis patients on their quality of life

Design

Patients will then be divided into intervention and control groups after obtaining criteria for entering the research using sealed envelopes. The sample size was obtained using the same studies using the mean comparison formula, with a 95% confidence interval and 95% probability test, about 18 samples for each group. Considering the probability of a 10 percent drop in samples, 20 patients will be selected for each group and a total of 40 patients.

Settings and conduct

Research will be weekly meetings of spiritual care education. Within six weeks, the components of insight and spiritual well-being will be taught to the Hemodialysis patients in the control group in groups of 5 to 8. Meetings will be held in a quiet place with suitable space at Allameh Bohlool Hospital in Gonabad University of Medical Sciences. Religious images and landscapes of nature, Quranic verses and spiritual poems will be used to accommodate the room space. The staff and staff of the Hemodialysis department of the intervention and control group will be unclear.

Participants/Inclusion and exclusion criteria

Participants in this research are hemodialysis patients at Allame Bohlool Hospital in Gonabad. From entering the research, being Muslim, aged 18 to 70, having a case in the hemodialysis department, having a willingness to study, having reading and speaking skills in Persian. Patients should be aware of the location and time and have a history of more than six months of hemodialysis. Participants in the study should have at least one weekly dialysis program.

Intervention groups

Intervention groups will consist of forty patients. Patients will be randomly assigned to control and intervention groups. In the control group, after learning and explaining the goals of the research, an educational program based on insight and spiritual action will be implemented. The number of sessions is six sessions that will run weekly for forty-five to sixty minutes. In the control group after the meeting, familiarization and completion of demographic questionnaires and the quality of life of renal patients, no further action will be taken. At the end of the study, the quality of life questionnaire for renal patients will be completed again by both groups.

Main outcome variables

Quality of life in Hemodialysis patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180212038702N1**
Registration date: **2018-02-23, 1396/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-23, 1396/12/04**
Update count: **0**

Registration date

2018-02-23, 1396/12/04

Registrant information

Name

Alireza zahrayi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 5722 3028

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-02-18, 1396/11/29
Expected recruitment end date
2018-06-20, 1397/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of education based on spiritual insight and action to Hemodialysis patients on their quality of life.

Public title
The effect of education based on spiritual insight and action to Hemodialysis patients on their quality of life.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being Muslim Having a desire to enter the research The patient has a case in the Hemodialysis department. At least 6 months have passed initiation of dialysis. Literacy is the ability to read and write Persian. Hearing and being aware of time and place Age more than 18 years and under 70 years Perform at least one dialysis session during the week
Exclusion criteria:
Absence of more than 1 session in training classes Immigration of the patient or death of the patient during the study Cancel people to continue their research Getting out of Hemodialysis treatment because of kidney transplant surgery or change in peritoneal dialysis Disorder of judgment and alertness of the patient
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples will be available as available. Among those who are eligible for inclusion criteria, they will be randomly allocated to intervention and control groups. Randomization will be done using sealed envelopes.
Blinding (investigator's opinion)
Not blinded
Blinding description
In this trial, while describing the purpose of the research to patients and the Hemodialysis staff, the intervention and control group for the Hemodialysis department staff will be unclear. Data will be analyzed and analyzed by someone other than the main investigator.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Gonabad University of Medical Sciences
Street address
Vahdat Avenue
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Approval date
2018-02-05, 1396/11/16
Ethics committee reference number
IR.GMU.REC.1396.119

Health conditions studied

1

Description of health condition studied
Quality of life of patients under Hemodialysis
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Quality of Life
Timepoint
The effect of spiritual care education on quality of life will be measured at the beginning of the study and within 4 weeks of the end of the intervention.
Method of measurement
A measure of the quality of life of the kidney patients in the Persian version of Imaninejad, which contains 79 items.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The intervention group will receive a training program based on insight and spiritual action. The duration of each session will be between 45 and 60 minutes, which will run on six sessions weekly. The components of spiritual health will be taught based on Islam. Three components of spiritual insight, spiritual action and spiritual emotions will be taught from two components of insight and spiritual action.

Category

Rehabilitation

2

Description

Control group: The control group was informed about the research goals and completed the demographic questionnaire and the quality of life questionnaire for renal patients. During the research period, no specific action will be taken for control group samples. The control group will receive routine care program. At the end of the research, the quality of life questionnaire will be completed by the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Allameh Bohlol Gonabadi Hospital
Full name of responsible person
Sajjadi Moosa
Street address
Vahdat Blvd
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Sajjadi Ali
Street address
Dr. Mahdizadeh Street
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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
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Sajjadi Moosa
Position
Assistant Professor of Nursing Education
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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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
No more info
Study Protocol
No - There is not 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
No - There is not a plan to make this available
Analytic Code
No - There is not 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 total potential data is then undetectable people sharing.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Certain conditions are not required.
From where data/document is obtainable
Deputy of Research and Technology of Gonabad University of Medical Scien
What processes are involved for a request to access data/document
The application should be submitted to the Deputy Director of Research and Technology of Gonabad University of Medical Sciences.
Comments
This study will be conducted in the School of Nursing.