

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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)

Phone

+98 51 5722 3028

Email address

zahrayi.ar@gmu.ac.ir

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

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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

Nursery

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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 Sciences

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.