Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of self-care education based on Orem theory on quality of life, adherence to treatment and self-care of hemodialysis patients

Protocol summary

Study aim

پDetermining the effect of educational program based on Orem self-care model on adherence to treatment, self-care behaviors and quality of life in hemodialysis patients

Design

The present study is a double-blind randomized clinical trial that will be performed on 80 patients with end-stage renal disease undergoing hemodialysis who are divided into intervention (40 patients) and control (40 patients) groups. The training intervention will be performed only for the intervention group and the control group will receive only the pamphlet and training package. Before, immediately and three months after the intervention, the questionnaire of quality of life, self-care and adherence to treatment will be completed for both intervention and control groups.

Settings and conduct

The study site will be the hemodialysis ward of Peymaniyeh Hospital in Jahrom. The study of randomized clinical trial will be double-blind

Participants/Inclusion and exclusion criteria

Inclusion criteria include: age 15 to 70 years, not attending training classes during the last 3 months, no mental health problems, having primary education, not having chronic diseases such as liver cirrhosis, end-stage cancer, having the ability for informed consent Exclusion criteria include: death of the patient, incompleteness of the questionnaire, kidney transplantation

Intervention groups

The training based on the Orem self-care model will be held virtually through 4 group classes of 20 people through WhatsApp program and phone message.

Main outcome variables

Adherence to treatment - quality of life - self-care behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044802N2**
Registration date: **2021-12-31, 1400/10/10**
Registration timing: **prospective**

Last update: **2021-12-31, 1400/10/10**
Update count: **0**

Registration date

2021-12-31, 1400/10/10

Registrant information

Name

Mostafa Bijani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5331 5012

Email address

bizhani_mostafa@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care education based on Orem theory on quality of life, adherence to treatment and self-care of hemodialysis patients

Public title

The effect of education on quality of life, adherence to treatment and self-care of hemodialysis patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria include: age 15 to 70 years, not attending training class during the last 3 months, no mental health problem, having primary education, no chronic disease such as liver cirrhosis, end-stage cancer, ability to consciously satisfy exit conditions : Death of the patient, incompleteness of the questionnaire, kidney transplantation

Exclusion criteria:

Exclusion criteria include: death of the patient, incompleteness of the questionnaire, kidney transplantation

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

More than 1 sample in each individual

Number of samples in each individual: **40**

40 people in the intervention group and 40 people in the control group

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is a simple random assignment, such as in an 80-card envelope with the letter A written on 40 cards and the letter B on the other 40 cards. Patients who meet the inclusion criteria are asked to pick up a card. If they pick up card A, they will be in the test group and if they pick up card B, they will be in the control group and this process will continue until the sample size is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is a double-blind study in which both participants and researchers or outcome assessors are unaware of the allocation of study groups.

Placebo

Not used

Assignment

Other

Other design features

The present study is a double-blind randomized clinical trial intervention that will be performed on 80 patients with end-stage renal disease undergoing hemodialysis who are divided into two groups of intervention and control. To determine the sample size, the average comparison formula in the two dependent groups will be used. In the study of the effect of applying the Orem self-care model on the quality of life of patients undergoing hemodialysis, conducted by Soleiman Naroui et al., 35 patients were selected as the sample size. The minimum sample size in each group in this study was 16 people. Due to the possibility of falling samples in the present study, 40 people will be selected in each groupOrem self-care model training through 4 groups of 20 people, which will be held virtually by WhatsApp and phone message due to coronary conditions. Classes will be held for 1 hour in the form of group discussions and lectures with educational pamphlets (due to coronary conditions and the need to prevent and control infection, especially in patients with end-stage renal disease, we tried to use educational booklets, educational pamphlets and telephone calls). After stating the objectives of the study for patients obtaining informed written consent during the first session of chronic renal failure, its cause, exacerbating factors, complications of the disease, its effects on life, exacerbating factors and improving and reducing factors in the second session with In the third session, the importance of participation in communities, weight care, sexual activity, exercise, self-care activities, and in the fourth session, the importance of adhering to the schedule, refer to The doctor will be instructed to refer to dialysis and follow the treatment. Educational pamphlets will also be provided to them. The scientific content of the training program will be designed and approved by 10 nursing professors and 5 kidney specialists. No educational intervention will be performed for patients in the control group and only pamphlets and educational content will be given to them. Before the training, immediately after the training and three months after the training in the control and intervention group, the questionnaire of quality of life, self-care and adherence to treatment will be completed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Fasa University of Medical Sciences

Street address

Ibn Sina Street. Fasa University of Medical Sciences

City

Fasa

Province

Fars

Postal code

7461686688

Approval date
2021-12-21, 1400/09/30
Ethics committee reference number
IR.FUMS.REC.1400.110

Health conditions studied

1

Description of health condition studied
Diseases of the urinary system
ICD-10 code
GC2Z
ICD-10 code description
Diseases of the urinary system

Primary outcomes

1

Description
adherence to treatment
Timepoint
Before, immediately and three months
Method of measurement
Treatment Adherence Questionnaire

2

Description
Self-care behaviors
Timepoint
Before, immediately and three months
Method of measurement
Self-care behavior questionnaire

3

Description
Quality of life
Timepoint
Before, immediately and three months
Method of measurement
Quality of life questionnaire for kidney patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Orem self-care model training through 4 groups of 20 people, which will be held virtually by WhatsApp and phone message due to coronary conditions. Classes will be held for 1 hour in the form of group discussions and lectures with educational pamphlets (due to coronary conditions and the need to prevent and control infection, especially in patients with end-stage renal disease, we tried to use educational booklets, educational pamphlets and telephone calls). After stating the objectives of the study for patients obtaining informed written consent during the first session of chronic renal failure, its cause, exacerbating factors, complications of the disease, its effects on life, exacerbating factors and improving and reducing factors in the second session with In the third session, the importance of participation in communities, weight care, sexual activity, exercise, self-care activities, and in the fourth session, the importance of adhering to the schedule, refer to The doctor will be instructed to refer to dialysis and follow the treatment. Educational pamphlets will also be provided to them. The scientific content of the training program will be designed and approved by 10 nursing professors and 5 kidney specialists.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Jahrom Peymaniyeh Hospital
Full name of responsible person
Samira Rezaei
Street address
Motehari street. Jahrom Peymaniyeh Hospital
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07461445135
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Dr. Mojtaba Farjam
Street address
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7461686688
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Email
Farjam@yahoo.com
Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice Chancellor for Research, Fasa 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
Fasa University of Medical Sciences

Full name of responsible person
Dr. Mostafa Bijani

Position
Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data is potentially shareable after unidentified individuals

When the data will become available and for how long
Until the end of 1401

To whom data/document is available
Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Access to the data and documentation will be provided upon request and approval of the research team members

From where data/document is obtainable

The main executor of the project is Dr. Mostafa Bijani. Fasa Medical Sciences

What processes are involved for a request to access data/document

Receive a request to use the documentation and submit the documentation within 2 weeks

Comments