Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of therapeutic educational program on behaviors and attitude toward therapeutic adherence and laboratory parameters of hemodialysis patients

Protocol summary

Study aim

The purpose of this study is to determine the demographic information, to determine the mean score of attitude toward adherence to the regimen, to determine the mean score of attitude toward adherence to the regimen, to determine the mean score of biochemical and hematological values of patients, comparison of the mean score of attitude toward compliance with the treatment regimen, comparison of the mean score of behaviors of treatment regimen and the comparison of the mean values of biochemical and hematological laboratory values before, one and three months after the intervention, between the control and experimental groups in hemodialysis patients referring to Imam Reza hospital in Sirjan in 1395.

Design

In this study, 60 patients undergoing hemodialysis in Imam Reza hospital of Sirjan who were eligible to enter the study were selected. Participants were randomly divided into two groups of study and control groups by Coupled and odd days of the week.

Settings and conduct

In this study, after obtaining the code of ethics and oral satisfaction from patients undergoing hemodialysis in Imam Reza Sirjan Hospital to participate in the study, two groups of intervention and control completed the questionnaires. Data were collected through two researcher-made questionnaires, which were prepared using two questionnaires of Renal Adherence Attitude Questionnaire and Renal Adherence Behavior Questionnaire. Laboratory values were also performed with the coordination of the hospital and a specific kit. In the first stage of the intervention, after the assessment of the educational needs, the educational program was designed in the intervention group and given 3 sessions per week, face-to-face and individual. In the control group, regular education was given.Then, in both groups, the questionnaires were completed again one month and three months after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criterias are: Over age 14 years, hemodialysis for at least 6 months, hemodialysis 3 times per week and 3-4 times per week, and non-inclusion criteria are: renal transplant candidate, reluctance to continue participating the Study, being in the uremic phase of the disease and developing mental illness that prevents the patient from being properly contacted

Intervention groups

In this study, the study groups included the intervention group and the control group. The intervention group received an educational written program in face-to-face and individual sessions at intervals of one week for 3 sessions. The control group received routine training. Questionnaires were completed in both groups before, one month and three months later.

Main outcome variables

Attitude toward adherence to the regimen; attitude toward adherence to the regimen; laboratory parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170116031972N3**
Registration date: **2018-01-14, 1396/10/24**
Registration timing: **retrospective**

Last update: **2018-01-14, 1396/10/24**
Update count: **0**

Registration date

2018-01-14, 1396/10/24

Registrant information

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Mahlagha Dehghan Anari

Name of organization / entity
Kerman University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2016-12-25, 1395/10/05
Expected recruitment end date
2017-05-17, 1396/02/27
Actual recruitment start date
2016-12-25, 1395/10/05
Actual recruitment end date
2017-05-17, 1396/02/27
Trial completion date
empty

Scientific title
The effect of therapeutic educational program on behaviors and attitude toward therapeutic adherence and laboratory parameters of hemodialysis patients

Public title
The effect of educational program on the attitude and compliance of the treatment regime in hemodialysis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age range over 14 years Being at least 6 months under hemodialysis Hemodialysis 3 times a week and every 3-4 hours
Exclusion criteria:
Candid for kidney transplant Unwilling to continue participating in the study Being in the Uremic phase of the disease Having mental disease (self-reported) that prevents the patient from being properly contacted
Age
From **14 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **69**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Not 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 of Kerman University of Medical Sciences
Street address
Ebnesina St،Jahad Blvd، Somaye Crossroad، Kerman
City
Kerman
Province
Kerman
Postal code
7815789957
Approval date
2016-07-22, 1395/05/01
Ethics committee reference number
IR.KMU.REC.1395.164

Health conditions studied

1

Description of health condition studied
Chronic Renal Failure
ICD-10 code
N18.4
ICD-10 code description
Chronic kidney disease, stage 4 (severe)

2

Description of health condition studied
Hemodialysis
ICD-10 code
Z49.31
ICD-10 code description
Encounter for adequacy testing for hemodialysis

Primary outcomes

1

Description
Attitude toward adherence to treatment regimen
Timepoint
Before intervention, one month and three month after intervention
Method of measurement
By filling the questionnaire

2

Description
Behaviors of the treatment regimen
Timepoint
Before intervention, one month and three month after intervention
Method of measurement
By filling the questionnaire

3

Description
laboratory parameters
Timepoint
Before intervention, one month and three month after intervention
Method of measurement
By measuring the levels of blood hematology and biochemistry

4

Description
Adequacy of dialysis
Timepoint
Before intervention, one month and three month after intervention
Method of measurement
Using Kt/V and URR test to measure dialysis adequacy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: face to face and individual educational program that provided.
Category
Behavior

2

Description
Control group: No intervention in control group
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Emamm Reza Hospital of Sirjan, Dialysis Department
Full name of responsible person
Mohaddeseh Seteyesh
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Mehdi Ansari
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Ebnesina St،Jahad Blvd، Somaye Crossroad، Kerman
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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 of Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Mohaddeseh Setayesh
Position
M.S of Medical Surgical Nursing
Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

Master of Science

Latest degree

Master

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data can be shared after identifying individuals that are relevant to their original outcome.

When the data will become available and for how long

Starting the access period is 6 months after printing the results

To whom data/document is available

Access will only be available to scholars working in academic and academic institutions.

Under which criteria data/document could be used

The only analyzes used in the study are allowed for delivered data.

From where data/document is obtainable

Mohaddeseh Setayesh: setayesh.89.m@gmail.com

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

When requesting the data, contact the e-mail address and the relevant application, along with the email, and the reason for the request and call number.

Comments