

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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

##### Name

Mahlagha Dehghan Anari

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Country**  
Iran (Islamic Republic of)  
**Phone**  
+98 34 3132 5201  
**Email address**  
m\_dehghan@kmu.ac.ir

**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**

Hejrat blvd

#### **City**

Sirjan

#### **Province**

Kerman

#### **Postal code**

7815789957

#### **Phone**

+98 34 4234 0302

#### **Email**

setayesh.89.m@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kerman University of Medical Sciences

##### **Full name of responsible person**

Dr. Mehdi Ansari

##### **Street address**

Ebnesina St,Jahad Blvd, Somaye Crossroad, Kerman

##### **City**

kerman

##### **Province**

Kerman

##### **Postal code**

7815789957

##### **Phone**

+98 34 3252 6750

##### **Email**

setayesh.89.m@gmail.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 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  
**Street address**  
Razi School of Nursing and Midwifery, Haft Baghe Alavi  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7815789957  
**Phone**  
+98 34 4233 1947  
**Email**  
setayesh.89.m@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Mansooreh Azizzadeh Forouzi  
**Position**  
Master of Science  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Razi School, Haft Baghe Alavi, Kerman  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7617949546  
**Phone**  
+98 34331325219  
**Email**  
Forozy@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Mohaddeseh Setayesh  
**Position**  
Student Master of Medical Surgical  
**Latest degree**

Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Razi School of Nursing and Midwifery, Haft Baghe Alavi.  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7815789957  
**Phone**  
+98 34 4233 1947  
**Email**  
setayesh.89.m@gmail.com

## 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