

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The Effect of Collaborative Care Model On Self-Efficacy and Dietary Adherence on Hemodialysis Patients Referred To Taleghani Educational Hospital Center In Urmia In 2018

Protocol summary

Study aim

Determine and compare the mean of self-efficacy, dietary adherence scores, and laboratory parameters before and after the implementation of model within and between the intervention and control groups

Design

Clinical trial with control group, 21 patient in each group, simple randomization, double blind

Settings and conduct

Hemodialysis section of Taleghani Hospital. Patients referred to odd days and even days of the week are divided into control and intervention groups in a draw and randomly assigned a list of 21 patients in each group. After completing the informed consent form, self-efficacy questionnaire and compliance questionnaire The kidney patient's diet was completed and the steps of the participatory care model were implemented in the intervention group during the 7 sessions with a physician attending, and then completed the questionnaires again. The average of the parameters of the laboratory parameters will be reviewed at the beginning and one month after the end of the intervention. The information collected by the researcher from the research team is included in the software and analyzed

Participants/Inclusion and exclusion criteria

At least 3 months of dialysis history; Having literacy; Able to walk and stand; Not having mental and cognitive disorders; Attend all training sessions

Intervention groups

Intervention group, completion of a specific questionnaire before and after follow-up of model items in seven sessions; The control group, receive the usual training of the department

Main outcome variables

Improve self-efficacy and adherence to dietary restrictions in patients undergoing hemodialysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180730040641N1**

Registration date: **2019-08-18, 1398/05/27**

Registration timing: **retrospective**

Last update: **2019-08-18, 1398/05/27**

Update count: **0**

Registration date

2019-08-18, 1398/05/27

Registrant information

Name

Sahar Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3275 2378

Email address

kazemi.s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Collaborative Care Model On Self-Efficacy and Dietary Adherence on Hemodialysis Patients Referred To Taleghani Educational Hospital Center In Urmia In 2018

Public title

The Effect of Collaborative Care Model On Self-Efficacy and Dietary Adherence on Hemodialysis Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Lack of cognitive and psychological diseases based on patient records
The ability to stand on the weight
Have at least reading and writing skills
Pass a minimum of three months from the start of hemodialysis

Exclusion criteria:

Unwilling to continue participating in the study
Hospitalization due to other diseases
Patient death

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **21**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method in this study is random selection (drawn randomly) of patients referring to odd days and even days of the week as control and intervention groups and then based on entry and exit criteria, patients in odd days and even days of the week are simple randomly selected from the list of patient names.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients selected for intervention and control groups referring hemodialysis on different days, so the control and intervention group has no relationship with each other. Data entry into Spss software and analysis of results is done by another researcher, who is not involved in data collection and does not know the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Pardis Nazlou, 11 km of Nazlou Road, Urmia, Iran

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5714783734

Approval date

2018-09-05, 1397/06/14

Ethics committee reference number

IR.UMSU.REC.1397.176

Health conditions studied

1

Description of health condition studied

Diet and nutrition for Haemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Mean self-efficacy score based on self-efficacy questionnaire

Timepoint

At the beginning of the study and after the end of the intervention two months later

Method of measurement

based on self-efficacy questionnaire

2

Description

Adherence to the diet

Timepoint

At the beginning of the study and after the end of the intervention two months later

Method of measurement

Renal Adherence Behavior Questionnaire

3

Description

Laboratory Parameters (Sodium, Potassium, Phosphorus, Protein)

Timepoint

First and 2 months after the end of the intervention

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Collaborative care model steps are implemented in interventional patients in 7 sessions. In order to achieve the objectives of the model, the steps include 4 steps: 1- Motivation, 2- Preparation, 3. Fighting, 4. Evaluation, which will be foreseen for each stage of the actual program. Based on estimated hemodialysis time in the hospital, a questionnaire for patients in each group will be completed. Motivation Stage: In order to stimulate patients by establishing appropriate communication with them, familiarizing them with the available area and facilities, informing patients about chronic renal failure, its consequences and its harmful consequences will be briefly discussed. Educational needs assessment will be done by examining and identifying the patient's problems by taking a biography and conducting an interview, which will be completed during a session after filling the questionnaire during the course of the hemodialysis for 2 hours. Preparatory phase: The objectives of the model and timing of participatory training programs and follow-up will be determined (one-hour session). Fighting stage: Training sessions and follow-up sessions will be held at this stage (each session for 45 minutes), which includes: 1) the first collaborative training session 2) the second training coaching session 3) the first follow-up participation meeting 4) the second phase follow-up meeting Evaluation: Achievement of goals will be evaluated in the implementation stages of the model, and this assessment will be carried out in stages at the beginning and end of each training session. The steps in teaching the content will be simple and lecture-less. Implementation of the educational program in the stage of engagement in the form of 4 sessions in the classroom located in the hemodialysis department of Taleghani Educational Center of Urmia for 45 minutes individually and separately for patients. Educational information will also be provided in the form of pamphlets and educational pamphlets. The questionnaire is again completed immediately at the last session (third session) and two months later by the patients. The average of the parameters of the laboratory parameters will be examined at the beginning and two months after the end of the intervention. Meanwhile, the contents of the pediatric hemodialysis nursing books and nurses and the instruction book are approved by the doctors and nursing practitioners.

Category

Behavior

2

Description

Control group: Training and regular dietary consultations are provided by the department.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Educational Center, Urmia

Full name of responsible person

Sahar Kazemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

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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

Oroumia 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
Oroumia University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available