Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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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

City
Urmia

Province
West Azarbaijan

Postal code
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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Pardis Nazlou, 11 km of Nazlou Road,Urmia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
Pardis Nazlou, 11 km of Nazlou Road, Nursing and Midwifery School
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mohebbi_iraj@yahoo.co.uk
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

Full name of responsible person

Sahar Kazemi

Position

Ph.D. student of nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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دانشجوی دکتری پرستاری

Latest degree

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Other areas of specialty/work

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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