

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Family-Centered Empowerment Model on the Treatment Adherence in Hemodialysis Patients

Protocol summary

Summary

The aim of this study is investigate the effect of family centered empowerment model on the treatment adherence in hemodialysis patients. Eighty-four patients treated with hemodialysis for at least six months and three hemodialysis sessions per week that have inclusion criteria, participate in this study. In case of peritoneal dialysis, transplantaion or death, patient exclude of study. This clinical trial include two groups (42 patients in intervention group & 42 patients in control group) and is single (Expert statistics) blind. Before intervention, the related forms and questionnaires will complete. In the intervention stage, for family active member in intervention group, 5-7 empowerment sessions will done on based family centered empowerment model with four step contain perceived threat, self -efficacy, self-esteem and evaluation. First step will be done for increase perceived intensity and perceived sensivity. The aim to second step or self-efficacy through group problem solving is to understand the family active member from the problem and problem solving process. In the third step or self-esteem through educational participation, discussed contents in sessions by family active member will be trained to patient. Evaluation step contains process and final evaluation. In process evaluation, during sessions, family active member is evaluated for perceived threat, self -efficacy and self-esteem. Furthermore, after intervention, empowerment evaluation questionnaire will complete by patient and family active member. Final evaluation will be done one month after the completion of the empowerment evaluation questionnaire for investigate effectiveness model and with completion treatment adherence questionnaire and checklist for record laboratory and clinical indicators in both groups. The control group receives just routine interventions and after final evaluation, pamphlet and booklet will be available for them.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102824758N1**

Registration date: **2015-11-29, 1394/09/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-29, 1394/09/08

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

sabzevar university of medical sciences

Expected recruitment start date

2015-11-11, 1394/08/20

Expected recruitment end date

2015-12-11, 1394/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Family-Centered Empowerment Model on the Treatment Adherence in Hemodialysis Patients

Public title

The effect of family empowerment on the treatment adherence in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for patient and family active member: Willing to participate in the study; Age range 18 years and over; Reading and writing ability; Listening and speaking ability and acceptable consciousness to communicate; Lack of mental illness and cognitive impairment; Lack of participate in formal training sessions in the field of empowerment and treatment adherence at the same time; The weak or moderate score of empowerment evaluation questionnaire
Inclusion criteria for patient: Suffering of chronic renal failure and treatment with hemodialysis for at least six months; Three hemodialysis sessions in week and each session lasting 3-4 hours; Lack of other chronic disease; The weak or moderate score of treatment adherence questionnaire; Lack of physical limitations for self-care
Exclusion criteria for patient: Kidney transplant; Peritoneal dialysis or death during the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 Sabzevar University of Medical Sciences

Street address

School of Nursing and Midwifery, Next to The Police Station to Shahrud Road, Sabzevar

City

Sabzevar

Postal code**Approval date**

2015-08-16, 1394/05/25

Ethics committee reference number

IR.MEDSAB.1394.52

Health conditions studied**1****Description of health condition studied**

Hemodialysis patients

ICD-10 code

Z49

ICD-10 code description

Care involving dialysis

Primary outcomes**1****Description**

Treatment adherence

Timepoint

Before intervention- One month after the completion of the empowerment evaluation questionnaire

Method of measurement

Researcher made questionnaire

2**Description**

Empowerment

Timepoint

Before intervention- One week after intervention

Method of measurement

Researcher made questionnaire

Secondary outcomes**1****Description**

Laboratory and clinical indicators

Timepoint

Before intervention- After intervention

Method of measurement

Checklist for record laboratory and clinical indicators

Intervention groups**1****Description**

Intervention group: Family active member participate in 5-7 empowerment sessions in four steps: Perceived threat, self- efficacy, Self-esteem and evaluation.

Category
Behavior

2

Description

Control group: Get routine interventions in hemodialysis part and receive pamphlet and booklet after final evaluation.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Vasei Hospital
Full name of responsible person
Street address
Nuclear Martyrs Blvd, Sabzevar
City
Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Sabzevar University of Medical Sciences
Full name of responsible person
Mr. Moosa Reza Tadayonfar
Street address
School of Nursing and Midwifery, Next To The Police Station to Shahrud Road, Sabzevar
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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

Vice chancellor for research of Sabzevar University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty