Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of empowerment program based on BASNEF model on general health and self-efficacy of hemodialysis patients

Protocol summary

Summary

Objective: To determine the effect of empowerment program based on the BASNEF model on general health and self-efficacy of hemodialysis patients. Study design: Clinical trial, randomized, single-blind. The inclusion Main criteria: Chronic hemodialysis patients, aged 18 to 65 years and a willingness to Participating in research; the lack of history of known psychological problems and Known cognitive problems including Alzheimer's disease, stroke and transient ischemic attack. The exclusion main criteria: dissatisfaction with continuation of cooperation with the research, outbreak debilitating complications and death in studying subjects during the study. Sample size: 70 hemodialysis patients. Intervention: For intervention group patients, BASNEF-based empowerment program (in the field of Problems, feelings, opinions and thoughts of patients regarding hemodialysis and their lives, importance of hemodialysis, recognizing complications and their prevention and treatment, correct style of life in the fields of nutrition, exercise, self-care, anxiety and stress management, coping with negative attitudes, cognitive restructuring and patient's enabling factors) is performed by researchers. Intervention method so that Patients in groups (least 8 people and maximum 15 people) in 8 sessions 60 minutes (over 4 weeks and two days in a week), in a hemodialysis department in a place separate from hospitalized part of other patients, will participate. Patients in the control group underwent routine cares and educations and them will gave the hemodialysis patients special educational pamphlet. Intervention time: two months. Study outcomes: Increased levels of general health and self-efficacy of hemodialysis patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022514086N10**

Registration date: **2017-05-06, 1396/02/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-06, 1396/02/16

Registrant information

Name

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Name of organization / entity

Kashan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2017-04-09, 1396/01/20

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of empowerment program based on BASNEF model on general health and self-efficacy of hemodialysis patients

Public title
The effect of empowerment program based on BASNEF model on general health and self-efficacy of hemodialysis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: 1. Patients treated with chronic hemodialysis according to specialist diagnosis. 2. Willingness to participate in research. 3. Aged 18 to 65 years. 4. A history of well-known mental problems and kidney transplant is not. 5. Known cognitive problems including Alzheimer's disease, stroke, transient ischemic attack and hearing and vision loss to the extent that they cannot read or write; not suffered. 6. Physical and mental ability have to participate in empowerment meetings and be able to talk. 7. The caregiver is an important person for studying person and trust and confidence family and relatives his/her that directly involved in patient care. Exclusion criteria: 1. Dissatisfaction with continuation of cooperation with the study for any reason and at any phase 2. The absence in two or more sessions in the research program. 3. Outbreak debilitating complications of the disease. 4. Studying person died during the study.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
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
Kashan University of Medical Sciences
Street address
Vice Chancellor of Research & Technology, Kashan University of Medical Sciences, 5th km of Ravandi Ghotb Blvd, Kashan
City
Kashan
Postal code
8715988141
Approval date
2017-02-28, 1395/12/10
Ethics committee reference number
IR.KAUMS.REC.1395.145

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
General health
Timepoint
At baseline and a week after the last session implantation in the intervention group and after a month of the start of the study in the control group
Method of measurement
Goldberg's General Health Questionnaire

2

Description
self-efficacy
Timepoint
At baseline and a week after the last session implantation in the intervention group and after a month of the start of the study in the control group
Method of measurement
Sherer's General Self-Efficacy Scale

Secondary outcomes

empty

Intervention groups

1

Description
For intervention group patient, BASNEF-based empowerment program is performed by researchers. Intervention method so that Patients in groups (least 8 people and maximum 15 people) in 8 sessions 60 minutes (over 4 weeks and two days in a week), in a hemodialysis department in a place separate from hospitalized part of other patients, will participate. During the meeting's the program, about Problems, feelings, opinions and thoughts of patients regarding hemodialysis and their lives, the importance of

hemodialysis, recognizing complications and their prevention and treatment, the correct style of life in the fields of nutrition, exercise, self-care, anxiety and stress management, coping with negative attitudes, cognitive restructuring and patient's enabling factors, as group with lecture, group discussion and questions and answers methods will be discussed. According BASNEF model, in addition to the investigator and the patient, a meeting attended by treatment team members (Physicians, nurses and dietitian) and a meeting with a member of the patient family, will be held. In addition, the educational content in the form of a pamphlet available patient Family member will be, so that the education offered continuing more.

Category

Behavior

2

Description

Patients in the control group underwent routine cares and educations and them will gave the hemodialysis patients special educational pamphlet.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhavan Hospital

Full name of responsible person

Zahra Saeidnejad

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences, Vice Chancellor of Research & Technology

Full name of responsible person

Gholam Ali Hamidi

Street address

Vice Chancellor of Research & Technology, Kashan University of Medical Sciences, 5th km of Ravandi Ghotb Blvd, Kashan

City

Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan University of Medical Sciences, Vice Chancellor of Research & Technology

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

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Aghajani

Position

MSN, PhD Student in Nursing/ Instructor

Other areas of specialty/work

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Web page address

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