

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Assessing the effectiveness of the educational intervention based on self-efficacy on promoting self-care in hemodialysis patients

Protocol summary

Summary

The goal of this study is determine the effectiveness of the educational intervention based on self-efficacy on promoting self-care in hemodialysis patients. This is a quasi-experimental study that conducts in 2016. The research population consists of 70 hemodialysis patients referring to dialysis unit of Kamkar-Arabnia hospital in Qom city and they are randomly allocated to intervention (n=35) and control (n=35) groups. This study is performed in single center and is not blinded. Inclusion criteria includes age between 20-60 years; be able to read and write; lack of the mental disorders; having suitable physical condition and willingness to participate in the study, exclusion criteria includes Kidney transplantation, migration and patient death during the intervention. After completing informed consent by patients, data are collected from the samples of both groups by 3 questionnaires and through organized interview. The educational program based on self-efficacy theory is performed for the experimental group in 2 one-hour sessions. The issue of this sessions is self-care in dimensions: nutrition and diet, care of fistula and etc. Educational sessions are performed through face-to-face, lecture, question-and-answer and group discussion. Training materials are pamphlet and booklet. Both groups are followed for 3 months after the intervention then will be performed a post-test. No educational intervention is done on control group. The primary outcome of this study is self-efficacy and secondary outcome is self-care.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071628948N1**

Registration date: **2016-09-24, 1395/07/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-24, 1395/07/03

Registrant information

Name

Tahereh Ramezani

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25 3885 8566

Email address

t_ramezani533@yahoo.com

Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2016-09-17, 1395/06/27

Expected recruitment end date

2016-12-17, 1395/09/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of the educational intervention based on self-efficacy on promoting self-care in hemodialysis patients

Public title

The impact of education on self-care hemodialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

(Inclusion criteria: age between 20-60 years; be able to read and write and capable of listening, speaking, and consciousness to answer questions; having hemodialysis sessions 3 times per week for 3-4 hours; lack of the physical chronic disorders such as heart, respiratory, liver debilitating diseases; lack of the mental disorders such as severe depression and hospitalization in a psychiatric hospital (according to medical records); having suitable physical conditions and willingness to cooperate in the study; be independent to perform self-care activities (such as walking and eating without help))
(Exclusion criteria: people who are not able to cooperate and give information; Kidney transplantation, migration and patient death during the intervention)

Age

From **20 years** old to **60 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)

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 Qom University of Medical Sciences

Street address

2nd floor, No. 83, lane 4, alleys 1/1, Safashahr street,
Qom, Iran

City

Qom

Postal code

Approval date

2016-06-22, 1395/04/02

Ethics committee reference number

IR.MUQ.REC.1395.37

Health conditions studied

1

Description of health condition studied

Chronic Renal Failure.

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease

Primary outcomes

1

Description

Self- efficacy

Timepoint

Before, 3 Months after intervention

Method of measurement

Strategies Used by People to Promote Health
questionnaire

Secondary outcomes

1

Description

Self-care

Timepoint

Before, 3 months after intervention

Method of measurement

Researcher-made questionnaire of Self-care

Intervention groups

1

Description

Intervention Group: After completing informed consent by patients, data are collected from the samples of experimental group by 3 questionnaires and through organized interview. Then educational content is developed and educational program based on self-efficacy theory is performed for the experimental group in 2 one-hour sessions. The issue of this sessions is self-care in six dimensions: nutrition and diet, care of fistula, control of fluids and electrolytes intake, care of skin, exercise and physical activity and mental health. Educational sessions are performed through face-to-face, lecture, question-and-answer and group discussion. Training materials are pamphlet and booklet. This group are followed for 3 months after the intervention then will be performed a post.

Category

Lifestyle

2

Description

Control group: No educational intervention is done on

control group and they are received only usual care. Data are collected from the samples of control group through organized interview before and 3 months after the intervention.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dialysis unit of Kamkar-Arabnia hospital

Full name of responsible person

Fereydoun Mashhadi

Street address

Dialysis unit, Kamkar-Arabnia hospital, 19 Day street, Qom, Iran

City

Qom

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Educational Deputy Qom University of Medical Sciences

Full name of responsible person

Dr Hasan Adeli

Street address

Iran, Qom, Saheli street, Qom University of Medical Sciences, 2nd floor

City

Qom

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Educational Deputy Qom 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****Name of organization / entity**

Faculty of Public Health, Qom University of Medical Sciences

Full name of responsible person

Tahereh Ramezani

Position

MSc Student in Health Education and Health Promotion

Other areas of specialty/work**Street address**

Faculty of Public Health, Ruhollah Square, Moallem Street, Qom, Iran

City

Qom

Postal code**Phone**

+98 25 3783 3595

Fax

+98 25 3783 3595

Email

t_ramezani533@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Center of studies and Development of Medical Education

Full name of responsible person

Siamak Mohebi

Position

PhD in Health Education and Health Promotion

Other areas of specialty/work**Street address**

3rd floor, No. 83, lane 4, alleys 1/1, Safashahr street, Qom, Iran

City

Qom

Postal code**Phone**

+98 25 3285 2740

Fax**Email**

mohebisiamak@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Faculty of Public Health, Qom University of Medical Sciences

Full name of responsible person

Tahereh Ramezani

Position

MSc Student in Health Education and Health Promotion

Other areas of specialty/work**Street address**

Faculty of Public Health, Ruhollah Square, Moallem Street, Qom, Iran

City

Qom

Postal code

Phone

+98 25 3783 3595

Fax

+98 25 3783 3595

Email

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