Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

The Effect of Supportive Educative Program on Caregiver’s Burden and Quality of life in Hemodialysis patients

Protocol summary

Summary

The purpose of this study is to determine the effect of supportive educative program on caregiver’s burden and quality of life in hemodialysis patients. This study is a randomized clinical trial. The members of this research are 76 people of caregivers of patients under hemodialysis in Hashemi Nejad Educational Treatment Center that they are a member of patient’s family and have the primary responsibility for care of patient at home and if they be absent in one of the training sessions, they will be excluded from study. Based on reference day, for the patient’s hemodialysis in one and couple days, caregivers randomly will be placed in intervention and control groups. Then Demographic, Caregiver’s burden (CBI) and Quality of life (SF-36) questionnaires are completed before conducting the research by caregivers. This Program includes 6 sessions for 1 hour during two weeks that the care method in home of hemodialysis patient during 2 sessions and problem-oriented coping skills during 4 sessions are trained by lecture, role playing, group discussion, question & answer with using slides and booklets to intervention group. 6 Week’s after intervention, the caregiver’s burden (CBI) and quality of life (SF-36) questionnaires will be completed by intervention and control group. And after intervention, to comply with ethical issues, Training booklet and Educational Content will be given to control group, then the information of questionnaires will be analyzed by statistical and descriptive tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809032769N1**
Registration date: **2015-05-30, 1394/03/09**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2015-05-30, 1394/03/09

Registrant information

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Recruitment status

Recruitment complete

Funding source

Reaserch Assistance of Iran University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Supportive Educative Program on Caregiver’s Burden and Quality of life in Hemodialysis patients

Public title

Supportive Educative Program on Caregiver’s in

Hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for patients: 1- Age 18 to 65 years old with hemodialysis program per week (three times per week and each time, 3-4 hours). 2- Have a primary caregiver at home. 3- No previous history of renal transplant. Inclusion criteria for caregivers: 1- caregivers should have the primary responsibility to care of the patient and should be a member of family. 2- Age more than 18 years old. 3- Have the ability to speak, read and write in farsi. 4- Do not any known mental or neurological disorder. 5-Caregivers should not be a member of medical staff. The exclusion criteria: 1-Occurrence of stressful events in family (divorce, financial crisis, death of the primary family members). 2-Participating in training courses related with research intervention program during the study. 3- The lack of willingness to continue participating during the study. 4-The absence of primary caregiver who receipts training even in one training session. 5-The patient should be a candidate for kidney transplant during the study. 6-Protecting other chronic patients except hemodialysis patient in the family.

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: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Caregivers in this study randomly will be placed in intervention and control groups Based on reference days, for the patient’s hemodialysis in one and couple.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Between The Highway Martyr Chamran and Martyr Sheikh Fazlullah Nuri, Martyr Hemmat Highway ,Tehran, Iran.

City

Tehran

Postal code

1997613883

Approval date

2015-03-11, 1393/12/20

Ethics committee reference number

93/ D/ 105/ 6175

Health conditions studied

1

Description of health condition studied

Hemodialysis - Chronic kidney disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

caregiver’s Burden

Timepoint

Pre test and Six Week’s after intervention

Method of measurement

Caregiver’s Burden index

2

Description

Caregiver’s Quality of life

Timepoint

Pre test and Six Week’s after intervention

Method of measurement

Quality of life sf-36

Secondary outcomes

empty

Intervention groups

1

Description

In this study, the intervention program consisted of 6 sessions training on how to care hemodialysis patient and problem-oriented coping skills (Communicating correctly, anger management, deep breathing) for adapting to the role of caregivers that will be divided into two separate parts and intervention program will be starts follows; first the learning part of how to care patients with hemodialysis at home will be trained during first two session and then the training part of problem-

oriented skills will be conducted during four next sessions, Each session will be one hour during two weeks with lecture, role playing, group discussion, Questions and answers by using slide and training booklet. The prepared training booklet in first session of training program will be given to the caregivers and it will be emphasized to study the issues of each session at home. During sessions, the researcher will encourage the caregivers to Q and A and group discussion about the questions and ambiguities. At the end of each session, the conclusion will be summarized by participants. Also, The Caregivers will be asked to exercise and repeat these skills at home. And during sessions, they should exercise the anger management and deep breathing skills as role playing in class. Also The Telephone number of researcher will be given to caregivers for solving the problems and answer to questions. In the first session, the researcher after its introduction, divides the caregivers into 5-8 people groups and then will be express the training program, the aim of the intervention and the importance of cooperation, Also the comments about end stage renal disease, its signs and symptoms, causes and treatments and the importance of hemodialysis will be given to patients. In the second session, care training at home about how to conduct and control the special activities such as patient transmission, providing personalized patient care (bathing, hygiene, clothing, physical activity, diet and medication, weight control and blood pressure and fistulas treatment) and adjusting the hemodialysis session and monitoring the patient's condition will be explained. Also, the problems and experiences of caregivers will be examined by group discussion. In third session, the importance of caregiver role and his/her adjustment with this role will be discussed and we will discuss about the compatibility problems conducted for caregivers. And in fourth session, issues about problem-oriented coping skills to properly communicate will be presented. And in the fifth and sixth sessions, will discussed about the warning signs of anger, the creator and resonator situation, how to control anger.

Category
Other

2

Description
For control group, the training will not give by researcher and routine approaches of educational Hashemi Nejad Medical Centers will be given to them that include educational pamphlets.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Hashemi Nejad Educative Treatment Center

Full name of responsible person
Mansooreh Ashghali Farahani

Street address
Iran School of Nursing and Midwifery,Yasami St., Vali Asr Avenue.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Assistance of Iran University of Medical Sciences

Full name of responsible person
Syed Ali Javad Mousavi

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Iran University of Medical Sciences, Between The Highway Martyr Chamran and Martyr Sheikh Fazlullah Nuri, Martyr Hemmat Highway ,Tehran, Iran.

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Research Assistance of Iran 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
Iran School of Nursing and Midwifery, Iran Universityof Medical Science

Full name of responsible person
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Position
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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