Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of a family education program on care burden and quality of life in family carers of hemodialysis patients

Protocol summary

Study aim
This study aimed to examine the effectiveness of a program of family education on burden care and quality of life in family caregivers of patients undergoing hemodialysis.

Design
A randomized controlled clinical trial study was conducted on 70 family caregivers hemodialysis patients. The subjects were equally allocated randomely into two groups of test and control group and a code allocated to each one of them.

Settings and conduct
This research was done in Noor and Ali Asghar and Zahra Marziyeh clinical centers of Isfahan. The test group received eight training sessions program of family education. Both groups answered the caregiver's burden questionnaire and quality of life questionnaire before, immediately and one month after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Interested in participating in the study; Being able to communicate, read and write in Persian; Care giver's age 18 years and older; Caring for patients who have undergone kidney replacement for at least 3 months; Not participating Caregiver in family education session before; Mental and physical health of caregiver; Not treating care giver with hemodialysis; Having at least elementary educational level for the caregiver; Not being in cure team; Not using other complementary therapies such as physical therapies, acupuncture, yoga and psychotherapy sessions during the study.

Intervention groups
In this research, participants in the test group participated in 8 sessions, 90 minutes of family education program. Participants in the control group participated in 4 sessions of group discussion.

Main outcome variables
Burden care; quality of life of family caregivers of patients undergoing hemodialysis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170812035635N2**
Registration date: **2018-03-01, 1396/12/10**
Registration timing: **retrospective**

Last update: **2018-03-01, 1396/12/10**
Update count: **0**

Registration date
2018-03-01, 1396/12/10

Registrant information

Name
Reza Sotodeh

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Research Dupty of Isfahan University of Sciences

Expected recruitment start date
2016-10-22, 1395/08/01

Expected recruitment end date
2017-01-19, 1395/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of a family education program on care burden and quality of life in family carers of hemodialysis patients

Public title
The effect of a family education on care burden and quality of life in carers of hemodialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria:Interested in participating in the study being able to communicate read and write in persian Care giver's age 18 years and older Caring for patients who have undergone kidney replacement for at least 3 months Participants are included in the study from each family member who is the main caregiver Take care only of a chronic illness in the family Not participating Caregiver in family education session before Not having features of psychosis and other psychiatric and physical disorders Not treating care giver with hemodialysis Having at least elementary educational level for the caregiver Not being in cure team Not using other complementary therapies such as physical therapies, acupuncture, yoga and psychotherapy sessions during the study

Exclusion criteria:
dealing with the crisis and the severe stress before the study Caregiver's refusion for participating in the research project

Age
From **18 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
Samples were randomly assigned to two groups of test and control using random number table.

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 of Isfahan University of Medical Sciences

Street address
Isfahan university of medical sciences, Hezarjarib Avenue

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Province
Isfehan

Postal code
6628479531

Approval date
2016-08-22, 1395/06/01

Ethics committee reference number
IR.MUI.REC.1395.3.950

Health conditions studied

1

Description of health condition studied
Chronic kideny disease(Hemodialysis)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Caregiver's burden

Timepoint
before the intervention, immidiately after the intervention and one month after the intervention

Method of measurement
Zarit caregiver burden questionnaire

2

Description
quality of life

Timepoint
before the intervention, immidiately after the intervention and one month after the intervention

Method of measurement
quality of life -WHO short form questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In this study, for patients in the test group, family education program was held for 8 sessions, 90 minutes,

twice a week. This program provided methods for reducing care burden and improving the quality of life by providing information about the end stag of kidney disease and suitable communication of caregivers to the patient.

Category

Rehabilitation

2

Description

Control group: participants in the control group participated in 4 sessions of group discussion and expressed their feelings and experiences.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor va Aliasghar hospital

Full name of responsible person

Dr Mohammad Shamas

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2

Recruitment center

Name of recruitment center

Zahra Marziyeh mediacal center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Saied Pahlavanzadeh

Position

MSc of psychiatric nursing, Nursing and Midwifery care Research Center, faculty member of psychiatri

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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