Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Study The effect of family-centered empowerment model on quality of life in renal transplant patients

Protocol summary

Summary

This study aimed to the effect of family-centered empowerment model on quality of life in renal transplant patients will be performed. In this clinical trial, 60 renal transplant patients referred to the transplant clinic of Urmia Imam Khomeini hospital will be selected by available sampling and randomly divided into two intervention and control groups and pre- and post-test will be performed. Inclusion criteria for patients: the the minimum literate to read and write, crossing the minimum three months after kidney transplantation, infectious disease or disability severe lack the ability to establish telephone contact with the patient, the lack of other classes and educational programs in the field of kidney transplant during the study. Family member active inclusion criteria Having at least to read and write literacy, ,not using other educational classes about kidney transplant postoperative of the study, the possibility to establish telephone contact with family members active, selected by the patient, the patient obey him, living with patient, one member of the family (father, mother, sister, brother, partner). : Exclusion criteria patient and family member active including lack of comply with the anticipated therapeutic intervention programs and empowerment sessions, the absence of a maximum of two sessions, the rejection of kidney transplants during the study. Interventions include empowerment active member of the family after sampling during 8 to 9 training sessions and group discussions will be done for 3 to 4 months. The main outcome variables: quality of life for kidney transplant patients will be measurement through questionnaires KTQ-25. Other consequences include promoting knowledge, self-efficacy, self-esteem of patients and the effect of family-centered empowerment model on quality of life in kidney transplant patients.

General information

Acronym
not used

IRCT registration information
IRCT registration number: **IRCT2016020217059N5**
Registration date: **2016-08-09, 1395/05/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2016-08-09, 1395/05/19

Registrant information

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Recruitment status
Recruitment complete

Funding source
Government sources

Expected recruitment start date
2016-03-17, 1394/12/27

Expected recruitment end date
2016-09-15, 1395/06/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study The effect of family-centered empowerment model on quality of life in renal transplant patients

Public title
The effect of family-centered empowerment model on quality of life in renal transplant patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: minimum age of 18 years and a maximum of 60 years, Having at least to read and write literacy, awareness to time and place, the ability to participate in meetings of the empowerment and completed the questionnaires, lack of mental disorder, Passing the minimum three months after kidney transplant,not having server infection or disability disease , possible establish telephone contact with the patient,have the file at the transplant clinic of Urmia , not used of the other classes and educational programs in the field of kidney transplant during the study. Family member active inclusion criteria included Completed consent form participate in the study, the minimum age of 18 years and maximum 60 years, Having at least to read and write literacy, awareness to time and place, , the ability to participate in meetings of the empowerment and accompany the patient, The ability to Completed questionnaire, lack of mental disorder, the possibility to establish telephone contact with family members active, selected by the patient, the patient obey him, living with patient, one member of the family (father, mother, sister, brother, partner) who lives with the patient or the patient has quick and easy access,not using other educational classes during the the study, family member active should be able to power and decision-making and the importance of understanding the patient's condition more powerful than others. Exclusion criteria: Exclusion criteria patient and family member active including failure to the completed consent form to participate in the study, lack of comply with the anticipated therapeutic intervention programs and empowerment sessions, the absence of a maximum of two sessions, the rejection of kidney transplants during the study, the use of other classes and educational programs about kidney transplant and postoperative care by patient and active member of the study.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study, specific questionnaire kidney transplant patients (KTQ-25) was used to measure quality of life.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Urmia University of Medical Sciences

Street address
Urmia - km 11 Sero Road/ Nazlo Pardis Building School of Nursing and Midwifery

City
urmia

Postal code
5756115111

Approval date
2016-03-11, 1394/12/21

Ethics committee reference number
IRUMSU.REC.1394.408

Health conditions studied

1

Description of health condition studied
Kidney transplant

ICD-10 code
Z94.0

ICD-10 code description
Kidney transplant status

Primary outcomes

1

Description
Quality of Life

Timepoint
Before the intervention quality of life for kidney transplant patients will be measure then have three or four months after the intervention.

Method of measurement
According to the questionnaires KTQ 25

Secondary outcomes

1

Description

Increased life expectancy

Timepoint

before intervention and three months after intervention

Method of measurement

before intervention and three months after intervention and questionnaire KTQ 25

2

Description

Not rejection of the transplanted kidney

Timepoint

before intervention and three months after intervention

Method of measurement

before intervention and three months after intervention and questionnaire KTQ 25

Intervention groups

1

Description

Intervention group: of family-centered empowerment model in four steps (perceived threat, problem solving, educational partnership and evaluation) will be used. The first step is the perceived threat and included 3-4 meeting educational debates. The first meeting topics about the physiology of the kidney, renal failure, symptoms, treatment, and the second meeting about kidney transplant, kidney transplant rejection causes, symptoms and complications of kidney transplant rejected will be. The third meeting about Care of after kidney transplant , including diet, drug use , drug side effects and preventing of possible infections will be. The second step or problem-solving within three meeting, about how to problem-solving with project scenario and group discussions and answer the questions active member patient will be. The third step or educational partnership within two training sessions 30 to 40-minute will be done using educational cards. the final step evaluation process will be done in two phases. The evaluation process will be in the form of questions and answers at the next meeting and final evaluation two months after the intervention by questionnaire KTQ25 will be.

Category

Other

2

Description

The control group will receive routine clinical care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

the Urmia Imam Khomeini University hospital

Full name of responsible person

-soghra pahang-MSc Student of Medical - Surgical Nursing

Street address

:Imam Khomeini University Hospital-ershad Ave-Modarres Blvd-Urmia-Iran-trancplant clinic

City

urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Urmia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebi

Street address

Orjhans Street, Resalat Blvd, Urmia

City

Urmia

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, Urmia 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Masoume Hemmati Maslakpak

Position

PhD in Nursing / Associate Professor/ Educational Assistant School of Nursing and Midwifery

Other areas of specialty/work

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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