

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of self-care education on the quality of life in renal transplant patients referring to Imam reza hospital in Tabriz, 2017-2018

Protocol summary

Study aim

The effect of self-care education on the quality of life in renal transplant patients referring to Imam Reza hospital in Tabriz, 2017- 2018

Design

Sample size consist of 60 patients in a blind, randomized clinical trial. By using the records number and the www.random.org site two intervention and control groups will be determined

Settings and conduct

A study in Imam Reza Hospital in Tabriz Individual face-to-face education with a booklet will be done for 3 sessions with 30 to 45 minutes intervals every two days.

Participants/Inclusion and exclusion criteria

Inclusive criteria is age range, 18-60 years old and ability to read and write, at least 5 days after kidney transplant ion and no suffering from physical inability and disability, psychiatric illness and other serious chronic diseases that disrupt quality of life like types of cancer or Alzheimer disease. They should have a tendency to participate in research. A phone call can be provided for them.

Exclusive criteria will be absence of more than one session of self-care education sessions, being reluctant to participate in the study, migration and death of participants.

Intervention groups

Kidney transplant patients will be studied in two control and intervention groups. Individual face-to-face education with a booklet will be done for 3 sessions with 30 to 45 minutes intervals every two days. The data collection tool KTQ-25 was be completed before and after the intervention, for both groups in Tabriz Imam Reza hospital.

Main outcome variables

quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160220026662N3**

Registration date: **2018-09-10, 1397/06/19**

Registration timing: **retrospective**

Last update: **2018-09-10, 1397/06/19**

Update count: **0**

Registration date

2018-09-10, 1397/06/19

Registrant information

Name

Nader Aghakhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4816

Email address

nader1453@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care education on the quality of life in renal transplant patients referring to Imam reza hospital in Tabriz, 2017-2018

Public title

The effect of self-care education on the quality of life in renal transplant patients referring to Imam reza hospital in Tabriz

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 and 60 years Ability to read and write At least 5 days after kidney transplant ion The desire to participate in the study A phone call can be provided for them No suffering from physical inability and disability, psychiatric illness and other serious chronic diseases that disrupt quality of life like types of cancer or Alzheimer disease

Exclusion criteria:

Lack of more than one session of self-care training sessions Unwillingness to continue participating in the study Death and immigration of people

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

Using the file number and www.random.org website, they were divided into intervention and control groups

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 Urmia University of Medical Sciences

Street address

Orjans Street, Resalat Blvd, Urmia, iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-01-03, 1396/10/13

Ethics committee reference number

Ir.umsu.Res.1396.350

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 score in the questionnaire KTQ-25

Timepoint

Complete the questionnaire before training and two months after the end of the last training session

Method of measurement

questionnaire KTQ-25

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Individual face-to-face education with a booklet will be done for 3 sessions with 30 to 45 minutes intervals every two days. The data collection tool KTQ-25 was completed before and after the intervention, for both groups in Tabriz Imam Reza hospital. The control group will be received routine training. The teaching will be designed and implemented by the researcher in three shifts in the morning, evening and night. The content of the teaching at the first session will be about the nature of the disease, its etiology, its clinical signs and symptoms, diagnosis and treatment, and complications of the disease. At the second session the principles of drug administration and the side effects of medications will be discussed. During the third session, diet, physical activity and self-care activities will be taught. Two months after the end of the last teaching session, at the time of referral to the clinic or doctor or by telephone, the KTQ-25 questionnaire for patients will be completed again.

Category

Other

2

Description

Control group: No intervention will be in the control group and this group of patients will receive routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam reza hospital

Full name of responsible person

Sanaz Jalali

Street address

Gholgasht Ave, Emamreza Hospital

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Tabriz

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East Azarbaijan

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emamrezahosp@Gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Rahim Baghaiee

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Pardis nazlu, 11km nazlou road

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rbaghaei2001@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Sanaz jalali

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Nader Aghakhani

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Email

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Sanaz jalali

Position

Nurse

Latest degree

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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