

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Clinical trial Comparing the effectiveness of educational- supportive program on quality of life and transplant acute complications in two groups of kidney transplant patients.

#### Protocol summary

##### Summary

This study is done to the investigate effect of educational supportive package on quality of life and transplant acute complications in kidney transplant patients. This study is quasi-experimental, non-randomized, available sample method, sample volume 72 person( each group 36 person). Patients with age of 18 to 60 years and ability of read and write can participate in study and they are omitted from the study upon appearance of transplant acute complications and prolonged hospitalization. By drawing lots between the two hospitals where the research is conducted, one place is allocated to test group and other to control group. On reaching the semi- study, for create equal conditions, groups study place is replaced. By obtaining a written consent indicating voluntary participation and prior to commencement of intervention, demographic and disease questionnaire and kidney transplant specific questionnaire is completed by two groups. Educational supportive package contains 5 educational meetings 20 to 30 minutes based on care issues, stress decrease methods and matching with conditions, after relative recovery and during hospitalization period is conducted by the researcher through face to face method. The guidebook and 5 to 10 minute telephone contacts for responding to the patient's questions are included in this program. Control group receives routine training and cares of the ward. 8 weeks after the commencement of intervention, the quality of life specific questionnaire is completed by the patient and researcher made checklist for transplant acute complications is completed by the researcher in two groups and then, they are compared by using statistical methods.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201607254443N21**

Registration date: **2017-06-21, 1396/03/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-06-21, 1396/03/31

##### Registrant information

###### Name

Masoumeh Zakerimoghadam

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2286 2160

###### Email address

zakerimo@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Tehran university of medical sciences

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2016-11-21, 1395/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Clinical trial Comparing the effectiveness of educational-supportive program on quality of life and transplant acute complications in two groups of kidney transplant patients.

## Public title

Effect of education and supportive on quality of life and transplant acute complications in kidney transplant patients.

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria: age 18-60 year; least ability to read and write; interest to participate in study; the first transplant is done in patient; the patient is not member of treatment team; no history of mental disease.

Exclusion criteria: hyper acute transplant complications; staying over 20 days in hospital.

## Age

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

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **72**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran university of medical sciences

##### Street address

Ghods street, Keshvarz boulevard

##### City

Tehran

##### Postal code

#### Approval date

2016-06-26, 1395/04/06

#### Ethics committee reference number

IR-TUMS-VCR- REC-1395-189: Ethics committee of Tehran university of medical sciences

## 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 and 8 weeks after intervention start

#### Method of measurement

Quality of Life specific questionnaire in kidney transplant patients(KTQ-25)

## Secondary outcomes

### 1

#### Description

Kidney transplant acute complications

#### Timepoint

8 weeks after intervention start

#### Method of measurement

Kidney transplant acute complications check list

## Intervention groups

### 1

#### Description

In test group, interventions are as follows: face to face educational meetings is in five times 20 to 30 minutes. In this meetings is discussed on the patient's condition and the chronic nature of disease. Need to permanent care and follow-up, medicinal regime and diet importance in maintaining health and survival of transplanted kidney, understanding the risks and symptoms of rejection, new style of life and how to deal with common issues is discussed. Express fears and worry and respond to their questions take place in this meetings. Stress decrease methods such as listening to favorite music, thinking distraction by using favorite pastime and draw attention to issues other than illness, relaxation and relax the muscles and chants calming and all matching methods with this conditions is in educational supportive program. The guidebook which contains the necessary care points is given to the patients upon discharge and 5 to 10 minute telephone contacts are included in this program on a weekly basis during 8 weeks( by emphasizing the necessary care points and responding to the patient's questions).

#### Category

Other

## 2

### Description

In control group no intervention is conducted by researcher and patients receive routine training and cares of the ward.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imamkhomeini hospital, Kidney transplant ward

##### Full name of responsible person

Zakerimoghadam Masoumeh

##### Street address

Eastern Nosrat street, Tohid square

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Shariati hospital- Kidney transplant ward

##### Full name of responsible person

Zakerimoghadam masoumeh

##### Street address

Eastern Nosrat street, Tohid square

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Tehran university of medical sciences

##### Full name of responsible person

Zakerimoghadam Masoumeh

##### Street address

Eastern Nosrat street, Tohid square

##### City

Tehran

#### 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 of Tehran 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

Nursing midwifery faculty of Tehran university of medical sciences

#### Full name of responsible person

Zakerimoghadam Masoumeh

#### Position

Nursing education PHD, Faculty member

#### Other areas of specialty/work

#### Street address

Eastern Nosrat street, Tohid square

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1419733171

#### Phone

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#### Email

zakerimo@gmail.com: zakerimo@sina.tums.ac.ir

#### Web page address

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Nursing midwifery faculty of Tehran university of medical Sciences

#### Full name of responsible person

Zakerimoghadam Masoumeh

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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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*