Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of education based on self-efficacy theory and the theory of self-management and integration of them in order to promote quality of life in kidney transplant recipients

Protocol summary

Summary

A quasi-experimental design was used to conduct the study which aimed to determine the effect of an educational intervention based on the self-efficacy theory on improving the quality of life for kidney transplant patients. Sample will be selected through a convenience sampling method with random allocation from the nephrology clinic of Imam Hospital of Ardabil. A sample of 115 patients have been estimated using the appropriate sampling formula, given the loss rate of 10%, 130 patients were estimated to include in the study. They will be eligible for this study if they have (1) receivers of kidney transplantation at least 6 months and no longer than 10 years prior, (2) aged at least 18 years old, (3) being in a stable health condition and (4) agreed to participate and to sign the written informed consent form. The questionnaire of quality of life (QoL), self-efficacy scale, self-management scale and psycho-physical stress scales for kidney transplant patients will be used to collect data. Then intervention based on self-efficacy theory and the theory of self-management and integration of them will be design, and educational content will be prepared. Designed combination intervention will be implemented only on Group 3; for group 1 an educational intervention based on the theory of self-efficacy and for Group 2 an educational intervention based on self-management theory will be done. Follow up assessments will be completed one month and six months after the intervention by the above mentioned questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121931482N1**

Registration date: **2017-02-09, 1395/11/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-09, 1395/11/21

Registrant information

Name

Aghil Habibi Soola

Name of organization / entity

Ardabil university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 45 3345 3662

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-02-08, 1395/11/20

Expected recruitment end date

2017-06-10, 1396/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on self-efficacy theory and the theory of self-management and integration of them

in order to promote quality of life in kidney transplant recipients

Public title
self-efficacy, self management and quality of life of kidney transplant patients
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria; have received a kidney transplant at least 6 months and no longer than 10 years prior be at least 18 years old and less than 65 years old be in a stable Medical condition Agree to participate exclusion criteria; have received a kidney transplant less than 6 months and more than 10 years be less than 18 years old and more than 65 years old be in an unstable Medical condition disagree to participate
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **130**
Randomization (investigator's opinion)
N/A
Randomization description
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 Iran University of Medical Science
Street address
Hemmat Highway, Tehran, Iran
City
Tehran
Postal code
Approval date
2016-02-22, 1394/12/03
Ethics committee reference number
IR.IUMS.REC.1394.27236

Health conditions studied

1

Description of health condition studied
kidney transplantation
ICD-10 code
T86.1
ICD-10 code description
Kidney transplant failure and rejection

Primary outcomes

1

Description
self efficacy
Timepoint
pre intervention, one month and six months after intervenyion
Method of measurement
The Kidney Transplantation Self-Care Self-Efficacy Scale

2

Description
self management
Timepoint
pre intervention, one month and six months after intervenyion
Method of measurement
The Kidney Transplantation Self-Management Scale

Secondary outcomes

1

Description
quality of life
Timepoint
pre intervention, one month and six months after intervention
Method of measurement
Short Form Health Survey (SF-36) Questionnaire

2

Description
depression
Timepoint
pre intervention, one month and six months after intervention
Method of measurement
Beck Depression Inventory

Intervention groups

1

Description
Intervention 1; For group 1, intervention based on self-efficacy theory will be design, and educational content

will be prepared and done.

Category

Other

2

Description

Intervention 2; For Group 2, intervention based on self-management theory will be design and educational content will be prepared and done.

Category

N/A

3

Description

Intervention 3; For group 3, intervention based on integration of self-efficacy theory and self-management will be design and educational content will be prepared and done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nephrology clinic of Imam Hospital of Ardabil

Full name of responsible person

Vahed Alaee

Street address

Imam Hospital- Ataee street- Ardabil

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Mrs.Golband

Street address

Hemmat Highway

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, 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 University of Medical Science

Full name of responsible person

Aghil Habibi

Position

PhD student

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