Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Investigate the effect of self-management programs on quality of life in patients with kidney transplant

Protocol summary

Summary

This study was conducted with the aim to determine the effect of self-management program on quality of life for kidney transplant patients referred to Isfahan's Charity Center of Hazrat-e-Abolfazl (AS) in 2015. This study is a clinical trial with two groups and three stages which was conducted before, immediately, and three months after the intervention. In this research, the impact of independent variable of self-management program on the dependent variable of life quality was evaluated in kidney transplant patients. Research environment is the Charity Center of Hazrat-e-Abolfazl (AS). The main inclusion criterion: a minimum age of 18 years; at least three months have passed from the time of their kidney transplant; And the main criterion for exclusion was absence of more than one session in the training sessions; hospitalization or death during the study. A total of 64 kidney transplant patients who met the inclusion criteria, were recruited by convenience sampling method. Eventually, selected samples were randomly put in two intervention group (n = 32) and control group (n = 32). After putting the patients into two intervention and control groups, the intervention group received self-management training program in chronic diseases. This training program was a 15-hours community-based program that was provided at 2.5-hour meetings during 6 weeks. The study lasted about a month. A session was also held for the control group with educational content diet. Information in this study was completed before, immediately, and three months after in questioning way by using Quality of Life Questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062828457N4**
Registration date: **2016-07-24, 1395/05/03**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-07-24, 1395/05/03

Registrant information

Name
Somayye Kuwaity
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

Isfahan University of Medical Sciences

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigate the effect of self-management programs on quality of life in patients with kidney transplant

Public title

Self-management program impact on the quality of life in patients with kidney transplant

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Minimum age of 18 years; At least three months have passed from the time of their kidney transplant; Capable of reading and writing in Persian language to complete a questionnaire; They do not simultaneously participate in another study ; Willingness to participate in the study ; Have no mental retardation, blindness and deafness. Exclusion criteria: Unwillingness of the patient to continue for participating in the study; Hospitalization or death during the study ; Absence of more than one session in training sessions.
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
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
Isfahan University of Medical Sciences
Street address
Hezar Jerib Avenue, Isfahan University of Medical Sciences, School of Nursing and Midwifery, Isfahan
City
Isfahan
Postal code
81746-73461
Approval date
2016-01-20, 1394/10/30
Ethics committee reference number
394732

Health conditions studied

1

Description of health condition studied
Kidney transplant patients
ICD-10 code
z94.0
ICD-10 code description
Kidney transplant status

Primary outcomes

1

Description
Quality of life
Timepoint
Before, immediately, and three months after intervention
Method of measurement
Quality of Life Questionnaire for patients with renal transplantation

Secondary outcomes

1

Description
Quality of life
Timepoint
Before, immediately, and three months after intervention
Method of measurement
Quality of Life Questionnaire for patients with renal transplantation

Intervention groups

1

Description
Intervention group: Workshops were held weekly over a six week period, with each session taking 2.5 h to complete.
Category
Lifestyle

2

Description
control group: Received a training session on nutrition
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan’s charity society of Hazrat-e-Abolfazl (AS)
Full name of responsible person
Ahmad Famil Dardashti
Street address
In front of Poshte Matbakh alley, Ostandari Street , Isfahan
City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Ashraf Kazemi

Street address
Hezar Jerib Avenue, School of Nursing and Midwifery, Isfahan-

City
Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Isfahan 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
Isfahan University of Medical Sciences

Full name of responsible person
Somayye Kuwaity

Position
M.A student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Faculty of Isfahan Medical Sciences University

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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