

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 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

Country

Iran (Islamic Republic of)

Phone

+98 933 241 0966

Email address

somayyekuwaity@nm.mui.ac.ir

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

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

Street address

Isfahan University of Medical Sciences Dormitory,
Isfahan

City

Isfahan

Postal code

7976113974

Phone

+98 76 4465 3210

Fax

+98 31 3669 9398

Email

somayyekuwaity@gmail.com
somayyekuwaity@nm.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Ahmad Ghadami

Position

Faculty of Isfahan Medical Sciences University

Other areas of specialty/work

Street address

Koi Safikhani, Bahariyeh 2, Artesh Street

City

Isfahan

Postal code

8174673461

Phone

+98 76 4465 3210

Fax

+98 31 3669 9398

Email

somayyekuwaity@gmail.com
somayyekuwaity@nm.mui.ac.ir

Web page address

Person responsible for updating data

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

Street address

Isfahan, Isfahan University of Medical Sciences
Dormitory

City

Isfahan

Postal code

7976113974

Phone

+98 76 4465 3210

Fax

+98 31 3669 9398

Email

somayyekuwaity@gmail.com
somayyekuwaity@nm.mui.ac.ir

Web page address

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