Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of expressive emotion intervention effect on physical and mental health of kidney transplant recipients

Protocol summary

Summary

Although Kidney transplant as an alternative treatment can increase life expectancy and improve the quality of life of patients with end-stage kidney function ,it is associated with a lot of mental stress and psychiatric co-morbidity for these patients. The aim of this study is to evaluate of expressive emotion effect on physical and mental health of kidney transplantation recipients. In this clinical trial transplant recipients randomly will divide into two intervention and control groups and respectably will receive expressive emotion therapy and daily recording method as placebo. Effect of these methods on quality of life, general health, anxiety, depression and medical complications will be assessed by Hospital Anxiety Depression Scale(HADS), General Health Questionnaire(GHQ) and Kidney Transplant Questionnaire(KTQ) .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111625063N1**
Registration date: **2016-01-11, 1394/10/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-01-11, 1394/10/21

Registrant information

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Tehran University of Medical sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of expressive emotion intervention effect on physical and mental health of kidney transplant recipients

Public title

Evaluation of expressive emotion intervention effect on physical and mental health of kidney transplant recipients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusive criteria: Patients under kidney transplantation; During 1st week after transplant; Age >18 years old; With ability of writing and reading in Farsi. Exclusive criteria: No interest for participation in this study; Patients with prominent cognitive or psychiatric problem that limit their ability for participation in this study

Age

From **18 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
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of Tehran University of Medical Sciences
Street address
The Ethics Committee of Tehran University of Medical Sciences,Tehran University of Medical Sciences,Tehran , Iran
City
Tehran
Postal code
Approval date
2015-08-29, 1394/06/07
Ethics committee reference number
IR.TUMS.REC.1394.661

Health conditions studied

1

Description of health condition studied
Moderate Depression
ICD-10 code
F32.1
ICD-10 code description
Moderate depressive episode Four or more of the above symptoms are usually present and the patient is likely to have great difficulty in continuing with ordinary activities.

Primary outcomes

1

Description
Depression
Timepoint
1st and 3th month after intervention
Method of measurement
Questionnaire

2

Description
Anxiety
Timepoint
1st and 3th month after intervention
Method of measurement
Questionnaire

3

Description
Quality of life
Timepoint
1st and 3th month after intervention
Method of measurement
Questionnaire

4

Description
Medical complication
Timepoint
1st and 3th month after intervention
Method of measurement
History taking

5

Description
General health
Timepoint
1st and 3th month after intervention
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention for target group is expressive emotion therapy. During the first week after transplantation the target group will be asked to do homework in three 15 minutes sessions. How to write the contents of the cases will be as follows: What you are being asked to write, as the most profound ideas, your feelings about the experience kidney failure and transplants. I know people who are undergoing a kidney transplant, experiencing many emotions and you want to focus on all of these

emotions. Discover your deepest feelings and thoughts. You may have different feelings and changes before the diagnosis of kidney failure, during dialysis, when you were in waiting list and now. Each of the courses you choose is important to focus entirely on your deepest feelings and thoughts. I mention again you must focused on the deepest feelings and thoughts. The only rule is continuous writing for 15 minutes. If you feel that you have nothing to give, just repeat the previous entries that have said. About the mistakes of grammar, spelling and sentence do not apply. Just write. After the meetings about the content of the supportive feedback is given by the clinician.

Category

Behavior

2

Description

The control group will be asked to focus only on the facts of renal failure and kidney transplantation, not on their emotions ,during three 15 minutes sessions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Arvin Hedayati

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Tehran University of Medical Sciences ,Deputy of Research and Technology

Street address

Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Tehran University of Medical Sciences

Full name of responsible person

Arvin Hedayati

Position

Fellowship Assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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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