Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effects of peer education on depression, anxiety, stress،quality of life and adherence among patients receiving dialysis

Protocol summary

Study aim

This study conduct to investigate the effects of peer education on depression, anxiety, stress,quality of life and adherence among dialysis patients.

Design

In this research, 76 eligible patients referring to Ali-Asghar dialysis center were chosen purposefully and were randomly divided into two groups of control and intervention.Due to the characteristics of the study intervention, blinding and allocation concealment are not applicable for this study.

Settings and conduct

Study population consist of all 130 dialysis patients who referee in 2017 to Ali Asghar teaching hospital, Isfahan, Iran.Due to the characteristics of the study intervention, blinding and allocation concealment are not applicable for this study.

Participants/Inclusion and exclusion criteria

Eligibility criteria are definite diagnosis of renal failure, a history of receiving dialysis for more than three months, no history of cognitive problems such as memory impairment, and no simultaneous participation in peer education programs. Recruit patients are excluded if they voluntarily chose to withdraw from the study, incompletely filled out study questionnaire, hospitalized in hospital, or underwent kidney transplant surgery during the study.

Intervention groups

Patients in the intervention group provide with peer education, while their counterparts in the control group solely receive routine care services which include no education by peers. For peer education, some patients need to be mentors for patients in the intervention group. Accordingly, patients with close treatment adherence and good self-management were identified by the head nurse, staff nurses, and attending nephrologists of the study setting. Then, eight 1.5-hour training sessions hold for mentors in order to improve their knowledge. Sessions hold thrice a week in days in which they did not receive dialysis. After these eight training sessions for mentors, patients in the intervention group divide into five six-patient groups . Grouping of patients is done based on their age, gender, marital status, income level, educational status, and weekly dialysis plan. In other words, patients in each group are almost homogeneous in terms of their age, gender, marital status, income level, educational status, and weekly dialysis plan. Then, peer education sessions are hold by mentors in the days of their allocated patients' dialysis, either before or after dialysis. Each mentor hold two 120-minute peer education sessions per week for eight successive weeks—sixteen sessions in total. During sessions, each mentor and his/her group members discuss and share their experiences and opinions about their problems, treatment regimens, dietary regimens, coping strategies, vascular access line care, and pre and post-transplantation care.

Main outcome variables

Depression,Anxiety,Stress,Quality of life,Adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171212037847N1**
Registration date: **2018-06-30, 1397/04/09**
Registration timing: **prospective**

Last update: **2018-06-30, 1397/04/09**
Update count: **0**

Registration date

2018-06-30, 1397/04/09

Registrant information

Name

Maryam Sadat Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3225 3349

Email address

maryam.hashemi@nm.mui.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2639-09-27, 2018/07/05

Expected recruitment end date

2639-12-26, 2018/10/05

Actual recruitment start date

2638-08-13, 2017/05/22

Actual recruitment end date

2638-12-13, 2017/09/22

Trial completion date

empty

Scientific title

Investigating the effects of peer education on depression, anxiety, stress،quality of life and adherence among patients receiving dialysis

Public title

Effects of peer education on depression, anxiety, stress،quality of life and adherence among patients receiving dialysis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients have definite diagnosis of renal failure, a history of receiving dialysis for more than three months no history of cognitive problems such as memory impairment no simultaneous participation in peer education programs

Exclusion criteria:

Recruited patients exclude if they voluntarily voluntarily chose to withdraw from the study patients exclude if they incompletely filled out study questionnaire patients exclude if they hospitalize in hospital patients exclude if they underwent kidney transplant surgery during the study.

Age

From **1999 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients receive dialysis either in odd or even days of the week,select in this study. In order to prevent the leakage of peer education information from the intervention group to the control group, patients who receive dialysis in even days randomly allocate to the intervention group, while patients who receive dialysis in the odd days randomly allocate to the control group. Random allocation do via the coin tossing method by a nurse who is external to the study. Sampling do randomly in the following steps. Initially, the name of each patient who receive dialysis in even days write on a card. Then, all cards mix and place in a bag. After that, one card randomly draw from the bag and the intended patient recruit to the intervention group. The card then return to the bag and a new card select for the next patient. The same process repeat until the determined number of patients recruit. Patients for the control group also recruit through the same process. Due to the characteristics of the study intervention, blinding and allocation concealment not applicable for this study.

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 Isfahan University of Medical Sciences

Street address

Noor and Hazrat-e-Ali Asghar Hospital,Hasht Behesht Ave., Ostandari St., Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8199875784

Approval date

2017-03-17, 1395/12/27

Ethics committee reference number

IR.MUI.REC.1395.3.293

Health conditions studied

1

Description of health condition studied

Chronic kidney disease, stage 5

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description
Depression
Timepoint
Patients' depression assess before and immediately and 1 month after the intervention via the 42-item Depression Anxiety Stress Scale (DASS-42).
Method of measurement
Patients' depression assess via the depression Anxiety Stress Scale -42 Item(DASS- 42)

2

Description
Anxiety
Timepoint
Patients' anxiety assess before and immediately and 1 month after the intervention via the 42-item Depression Anxiety Stress Scale (DASS-42).
Method of measurement
Patients' anxiety assess via the depression Anxiety Stress Scale -42 Item(DASS- 42)

3

Description
stress
Timepoint
Patients' stress assess before and immediately and 1 month after the intervention via the 42-item Depression Anxiety Stress Scale (DASS-42).
Method of measurement
Patients' stress assess via the depression Anxiety Stress Scale -42 Item(DASS- 42)

4

Description
Quality of life
Timepoint
Patients' quality of life assess before and immediately after the intervention via the Kidney Disease Quality of Life–Short Form version 1.3 (KDQOL-SF ver. 1.3)
Method of measurement
Patients' quality of life assess via the Kidney Disease Quality of Life–Short Form version 1.3 (KDQOL-SF ver. 1.3)

5

Description
Adherence
Timepoint
Patients' adherence assess before and immediately after the intervention via the end-Stage Renal Disease Adherence Questionnaire (ESRDAQ)
Method of measurement
Patients' adherence assess via the end-Stage Renal Disease Adherence Questionnaire (ESRDAQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: peer education
Category
Rehabilitation

2

Description
Control group: routine care services
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor and Hazrat-e-Ali Asghar Hospital
Full name of responsible person
Maryam Sadat Hashemi
Street address
Noor and Hazrat-e-Ali Asghar Hospital,Hasht Behesht Ave., Ostandari St., Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8199875784
Phone
+98 31 3225 3349
Email
Maryam.hashemi@nm.mui.ac.ir
Web page address
http://nour.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Maryam Sadat Hashemi
Street address
Noor and Hazrat-e-Ali Asghar Hospital,Hasht Behesht Ave., Ostandari St., Isfahan, Iran
City
Isfahan
Province

Isfehan
Postal code
8199875784
Phone
+98 31 3225 3349
Fax
+98 31 3669 9398
Email
maryam.hashemi@nm.mui.ac.ir
Web page address
http://nm.mui.ac.ir/en/contact-us
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

2

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr Shaghagh Haghjoy Javanmard
Street address
Isfahan University of Medical Sciences, Faculty of Nursing &Midwifery Hezar-jereeb Avenue, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673465
Phone
+98 31 3668 7153
Fax
+98 31 3669 9398
Email
maryamhashemi956@gmail.com
Web page address
http://nm.mui.ac.ir/en/contact-us
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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Maryam Sadat Hashemi
Position
PhD candidate in nursing of Isfahan university medical science, Department of Critical Care, School
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
No: 20, Memarzade Alley, Sepenta Avenue, Isfahan, Iran.zip Code: 81999-47741.
City
Isfahan
Province
Isfehan
Postal code
8199875784
Phone
+98 31 3225 3349
Email
Maryamhashemi956@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Maryam Sadat Hashemi
Position
PhD candidate in nursing of Isfahan university medical science, Department of Critical Care, School
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
No: 20, Memarzade Alley, Sepenta Avenue, Isfahan, Iran.zip Code: 81999-47741.
City
Isfahan
Province
Isfehan
Postal code

8199875784

Phone

+98 31 3225 3349

Email

Maryam.hashemi@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Sadat Hashemi

Position

PhD candidate in nursing of Isfahan university medical science, Department of Critical Care, School

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

No: 20, Memarzade Alley, Sepenta Avenue, Isfahan, Iran.zip Code: 81999-47741.

City

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Province

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Postal code

8199875784

Phone

+98 31 3225 3349

Email

maryam.hashemi@nm.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Researcher that work in academic and scientific institutes can access to demographic variable and main outcome such as depression, anxiety,stress, adherence, quality of life of this study.

When the data will become available and for how long

Academic and scientific researcher access to data, 6 months after publication result.

To whom data/document is available

Researcher that work in academic and scientific institutes can access to data.

Under which criteria data/document could be used

you can analyse data with SPSS but you do not access to confidential patient data.

From where data/document is obtainable

if you need to access to data,you can call with me or send email for me. Call number:00989134118910 Email: maryamhashemi956@gmail.con

What processes are involved for a request to access data/document

After I receive your request,I send them after 10 -30 days.

Comments