

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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 hospitalized 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**

Isfahan

**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**

## 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

## 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

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##### 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

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**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  
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**Web page address**  
<http://nm.mui.ac.ir/en/contact-us>  
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**Is the source of funding the same sponsor organization/entity?**  
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**Title of funding source**  
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**Proportion provided by this source**

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**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.  
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## **Person responsible for scientific inquiries**

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**Position**  
PhD candidate in nursing of Isfahan university medical science, Department of Critical Care, School  
**Latest degree**  
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**Other areas of specialty/work**  
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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

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## 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.com

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

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

**Comments**