

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of peer support on hope, acceptance of disability and social relational quality in patients undergoing hemodialysis referred to hemodialysis centers affiliated to Shiraz University of Medical Sciences 2018-2019.

Protocol summary

Study aim

The purpose of this study was to determine the effect of peer support on hope, acceptance of disability and social relational quality in patients undergoing hemodialysis referring to educational centers of Shiraz University of Medical Sciences.

Design

This is an interventional study and one-blind randomized clinical trial with control group. The sample will comprise 128 male and female hemodialysis patients. . Patients will be randomly divided into two groups according to the paired or referenced person. The systematic random method will then be used to identify individuals to enter the groups.

Settings and conduct

The research environment in this study includes hemodialysis centers affiliated to Shiraz University of Medical Sciences. On the one hand, the blindness of the study will be used to collect data and complete the questionnaires with the help of a researcher who is not aware of the division of the groups. Also, a statistics specialist who performs data analysis will be blind to groups

Participants/Inclusion and exclusion criteria

Patients should undergo hemodialysis for at least 6 months to enter the study. People with heart problems and cognitive problems will not be included in the study.

Intervention groups

Patients in both control and intervention groups will receive routine hemodialysis care. In the intervention group, the topics include the provision of various types of social protection (psychological, emotional, informational, tangible and social support) by the peer group, changes in physical and psychological complications such as muscle cramps, problems with sleep and itching, proper nutrition and sexual problems.

Main outcome variables

Hope, Acceptance of disability, Social relational quality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190126042498N1**

Registration date: **2019-04-20, 1398/01/31**

Registration timing: **prospective**

Last update: **2019-04-20, 1398/01/31**

Update count: **0**

Registration date

2019-04-20, 1398/01/31

Registrant information

Name

Mostafa Jowkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4333

Email address

stud2520080604@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-04, 1398/02/14

Expected recruitment end date

2019-07-10, 1398/04/19

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of peer support on hope, acceptance of disability and social relational quality in patients undergoing hemodialysis referred to hemodialysis centers affiliated to Shiraz University of Medical Sciences 2018-2019.

Public title
The effect of peer support on hope, acceptance of disability and social relational quality in patients undergoing hemodialysis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1.The age of the patients is between the ages of 18 and 60 years. 2.At least 6 months should be treated with hemodialysis. 3.Hemodialyzes at least 2 times a week and up to 3 times a week. 4.Willing to participate in the study.

Exclusion criteria:

1. The patient has advanced cardiovascular disease, such as heart failure and acute pulmonary edema. 2.The patient has sensory-neurological disorders such as hearing impairment and vision or cognitive impairment such as dementia. 3.The patient has drug addiction. 4. Patient faced with emotional crisis such as close relatives and divorce during the past 6 months. 5. Patients who are not willing to continue to work.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
After receiving the approval of the Ethics Committee of Shiraz University of Medical Sciences, the list of the research community is prepared according to the list of patients with active records in the selected hemodialysis centers of Shiraz University of Medical Sciences. Patients are randomly selected using random numbers tables. Then, to enter the groups, the days of the week are divided into two groups based on the random throwing of the coin. Accordingly, the patients were randomly assigned to one of the two control and intervention groups based on the pair and weekly days.

Blinding (investigator's opinion)

Single blinded
Blinding description
On the one hand, the blindness of the study will be used to collect the data and complete the questionnaires with the help of a researcher who is not aware of the division of the groups. Also, a statistics specialist who performs data analysis will be blind to groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Fars Province University of Medical Sciences and Health Services, Zand Avenue

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-02-05, 1397/11/16

Ethics committee reference number

IR.SUMS.REC.1397.1146

Health conditions studied

1

Description of health condition studied

Chronic renal failure.patients undergoing hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Hope score in Snyder questionnaire

Timepoint

At the beginning of the study and two months after the onset of peer support for hemodialysis patients

Method of measurement

Hope Snyder questionnaire

2

Description

Acceptance of disability score in acceptance of disability questionnaire

Timepoint

At the beginning of the study and two months after the onset of peer

Method of measurement

Acceptance of disability questionnaire

3

Description

Social relational quality score in social relational quality questionnaire

Timepoint

At the beginning of the study and two months after the onset of peer

Method of measurement

Social relational quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, in order to select the peer group, a list of hemodialysis patients from the selected hemodialysis centers of Shiraz University of Medical Sciences will be prepared and targeted and selected from among them who have the following conditions: willing to volunteer for participation In the study, they should be hemodialyzed for at least 6 months, have a good faculty, have the ability to organize sessions and have an interest in the leadership of the group, have a good relationship, are interested in education, are educated and willing to teach, while in the opinion of the expert physician Kidney and general practitioner of hemodialysis centers based on the evidence in the case, such as: Results of all tests and examinations, periodic medical and other specialists from complications of hemodialysis, the successful management of their disease. These criteria are based on the checklist according to the review of the texts and the standard terms of reference of the peer and according to the opinion of the professors. Finally, in order to provide peer support, 10 peers will be selected, who will be trained by the researcher during 3 two-hour training sessions. The first session focuses on the implications, the importance and benefits of peer support, the correct communication skills and how to provide tangible and peer support to the peer, and the second session on how to provide information support to peers (such as the necessary preparations and care before and after hemodialysis and activity At home and preventing the physical and psychiatric side effects of the disease). The third session also describes how psychosocial support is provided to peers as well as the

peace of mind. Further questions are answered by their counterparts and their beliefs are corrected on the basis of scientific sources. At the end of each session, Given is discussed. The method of teaching a researcher will be lecture, question and answer, and use of whiteboard. After each training session, the peer group will practice their training and support as a way of acting in the presence of the researcher. Subsequently, in order to ensure the readiness of the peers and to harmonize their education, the researcher will examine how the peers will be supported, according to the checklist prepared according to the items expressed in the three sessions. In the following, a booklet of all the materials presented in the meetings is provided to their counterparts. After preparing the group of peers, the patients, according to the pair or person to visit, were randomly selected using coin tossing in two groups Control and intervention. The systematic random method will then be used to identify individuals to enter the groups. The control group will receive routine hemodialysis treatment. In the intervention group, the sessions will be held once a week for 2 hours for 8 weeks for each of the groups before the onset of hemodialysis. For each group, the peer will be selected randomly and by gender. The peer group will train and support your group face to face with group discussion, question and answer, and troubleshooting issues. People from the group who are absent from 2 or less than 2 sessions will receive the topics discussed at the meeting by telephone from the researcher or peer group. The method of formation and management of the support group will be the same in all three groups and the issues of conscientiousness and culture will be observed during the sessions. At the first session, patients' health problems will be asked and then, according to priority, the subjects in each group, separately for the next seven sessions of the program It will be customized. Topics include the provision of various types of social support (psychological, emotional, informational, tangible and social support) by the peer group, changes in physical and psychological complications such as muscle cramps, problems with sleep and itching, proper nutrition and sexual problems. At each session, when discussing a disorder, approaches to adapt to changes and problems, to adapt to the state of being and to construct a new concept of life, to emphasize the use of experiences and opinions of others. Teaching slowly, teaching about disease and practices Controlling it, clarifying values, teaching thinking and self-management of emotions, and planning pleasure-pleasing activities are also discussed at these meetings. The titles of the sessions are almost the same in all three groups. In group of peers, the researcher is a facilitator, which leads to the effectiveness of the group. The researcher is responsible for facilitating group discussion, providing accurate scientific information, focusing on the group's dynamic process (lack of a person's control over the discussion, encouraging all members to discuss and solve the problem, facilitating members' communications, etc.), providing feedback to members, and paying attention to Law enforcement in the group. To prevent leakage of information, control and intervention groups are placed in separate shifts for

dialysis to not meet each other. Before and immediately after the end of the sessions, data are collected using a questionnaire.

Category

Lifestyle

2

Description

Control group: Patients in both control and intervention groups will receive routine hemodialysis care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz University of Medical Sciences- Namazi Hospital and Faghihi Hospital

Full name of responsible person

Nilofar pasyar

Street address

Namazi hospital, Zand Avenue

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3647 4254

Email

npasyar@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaeianzadeh

Street address

Shiraz University of Medical Sciences, Zand Avenue

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3647 4254

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Nilofar Pasyar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

No.342, Behesht Ave.Tachara

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3647 4254

Email

Npasyar@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nilofar Pasyar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

No.342, Behesht Ave.Tachara

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3647 4254

Email

Npasyar@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mostafa Jowkar

Position

master student of nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 7, Hijrat Street, Boulevard Azadi, shiraz Town

City

Shiraz

Province

Fars

Postal code

7143997487

Phone

+98 71 3647 4333

Email

mostafajowkar93@gmail.com

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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The following ethical considerations are considered in the implementation of the plan: - The principles of Helsinki in all stages of the study. - The principle of anonymity regarding questionnaires and their encoding. - Thank your permission from the relevant authorities at the college, university, and hospital. - Increase keeping participants' information and encoding questionnaires. - Understand the goals of the study and obtain informed consent from all participants. - Free freely from study in case of reluctance to cooperate. - Research results will be made available to participants and relevant organizations upon request.

When the data will become available and for how long

After the end of the study

To whom data/document is available

Research results will be made available to participants and relevant organizations upon request.

Under which criteria data/document could be used

The principle of anonymity regarding questionnaires and their encoding. - Thank your permission from the relevant authorities at the college, university, and hospital. - Increase keeping participants' information and encoding questionnaires

From where data/document is obtainable

Zand Street, Shiraz, Library of Shiraz Nursing and Midwifery Faculty. Mr. Qasemi Library Dept. Telephone: 00987136474254

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

The request for data is sent to the library of the Nursing and Midwifery Faculty of Shiraz. The coordination is done after one week of data being sent to them.

Comments