

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of peer support group on the care burden and unmet needs of caregivers of hemodialysis patients

Protocol summary

Study aim

Determining the impact of peer support group on care burden and unmet needs of caregivers of hemodialysis patients

Design

This clinical case study is conducted on 60 caregivers of hemodialysis patients, 30 people in each group are randomly selected according to the entry criteria, the study is a blind study.

Settings and conduct

Among the hemodialysis centers in Mashhad, two centers, 17 Shahrivar and Mantsariyeh, which are homogeneous with each other in terms of the cultural and social conditions of the clients, their economic class, and the location of the centers in the city, were selected, after which they were selected by drawing a lottery. Goi from Kise Dialysis Center on 17th of Shahrivar was considered as the intervention center and Mantasiriya as the control.

Participants/Inclusion and exclusion criteria

For caregivers: 1- Willingness to participate in the study 2- Being the main caregiver of the patient 3- History of at least 6 months of regular dialysis of the patient 4- Reading and writing literacy 5- Ability to make phone calls 6- Absence of specific psychological problem 7- Not being part of the health team 8- Lack of support from the support group
Peer entry criteria: 1- Being accepted by group members 2- Interest and motivation to play a role 3- Ability to manage meetings 4- Volunteering for training 5- Not having a history of mental and cognitive disorders 6- Having higher health literacy 7- Compatibility with care problems

Intervention groups

The participants are divided into two groups, in 17 Shahrivar hospital, peer experience sharing sessions will be held in order to reduce the burden of care and unmet needs, and in Mantasarih hospital, nursing training will be conducted according to the approvals of the patient education committee.

Main outcome variables

Caring burden, Support needs of caregivers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220724055540N1**

Registration date: **2022-08-11, 1401/05/20**

Registration timing: **prospective**

Last update: **2022-08-11, 1401/05/20**

Update count: **0**

Registration date

2022-08-11, 1401/05/20

Registrant information

Name

Nader Ghenaati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 709 5243

Email address

naderghenaati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-21, 1401/05/30

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of peer support group on the care burden and unmet needs of caregivers of hemodialysis patients

Public title

The effect of peer support group on the care burden and unmet needs

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The criteria for entering the research of caregivers: 1- Willingness to participate in the study and informed consent 2- Being the main caregiver of the patient 3- History of at least 6 months of regular dialysis of the patient 4- Reading and writing literacy 5- Absence of speech and hearing problems 6- Ability to make phone calls 7- Absence of mental problems Specific knowledge 8- Not being a part of the health team 9- Lack of support from the support group Peer entry criteria: 1- Acceptable and acceptable among other group members 2- Having interest and motivation to play a role 3- Ability to speak and conduct meetings with eloquent expression 4- Being a volunteer to teach others 5- Not having a history of mental and cognitive disorders 6- Having higher health literacy 7- More compatibility with care problems 8- Having proper communication skills

Exclusion criteria:

Having a history of mental and cognitive disorders Support by another support group Being part of the health team Having speech and hearing problems

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This semi-experimental study will be conducted on 60 caregivers of hemodialysis patients, first of all, two hemodialysis centers will be randomly selected from among public and private hemodialysis centers in which this plan can be implemented according to the required sample size. And then we consider one of these hemodialysis centers by lottery as the intervention center and the other as the center from which the control group is selected, 30 people in each group are randomly selected according to the entry criteria from among the private hemodialysis centers. and government in the city of Mashhad, after drawing lots, two centers in Hefdeh Shahrivar and Muntasarih were selected for sampling. They are homogenous and after

that, Hefdeh Shahrivar Dialysis Center was considered as the intervention center and Mantasariyeh as the control center by drawing a ball from the bag.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analysts who are responsible for entering sampling data and performing statistical tests are blinded to the data they are analyzing.

Placebo

Not used

Assignment

Parallel

Other design features

The number of sessions will be 8 sessions for the intervention group, two sessions for one hour each week in groups of 5 people. The subject of the peer support group meetings is based on the needs and interests of caregivers, which will be asked in the first meeting. Caregivers' needs that are raised more frequently and in more groups during the needs assessment session will be given higher priority to be raised in the support sessions and will be planned separately for the next seven sessions. At this stage, support meetings are held based on the importance of using group dynamics during the meetings and not one person riding on the time of the meeting, based on argumentative debate and nominal group techniques, so that every problem that is raised during the support meetings is discussed by all members. The group is placed and all the members have the right to comment and participate in the discussion, and the nurse and peer caregivers are encouraged to express their experiences and comment on the problems, and the caregivers are also asked to think, examine and analyze each other's solutions and methods of adaptation. and try to improve the mentioned solutions and experiences by providing their additional comments. In each meeting, the problem is first prioritized and discussed and experiences are shared according to the needs assessment meeting, then the peers receive feedback from the previous support meetings, and the way the caregivers use the materials mentioned in the previous meetings is questioned, and if new problems arise, These problems are evaluated by the nurse and peer and suggested solutions are provided to them by other caregivers. The community health nurse is present during the meetings and examines and analyzes the experiences and proposed solutions in order to modify and adjust unreasonable methods or dangerous, superstitious, unattainable and troublesome experiences in order to prevent the transmission of harmful experiences and causing losses. and avoid secondary risks

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Faculty of Nursing and Midwifery
, Mashhad University of Medical Sciences

Street address

College of Nursing and Midwifery, Chaharrah Doktra,
Ibn Sina Street, University of Mashhad, Razavi
Khorasan

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2021-11-30, 1400/09/09

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.023

Health conditions studied

1

Description of health condition studied

Kidney failure and hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Care burden

Timepoint

Before the intervention and one month after the
intervention

Method of measurement

Zarit Care Burden Questionnaire

2

Description

Unmet needs

Timepoint

Before the intervention and one month after the
intervention

Method of measurement

Questionnaire of support care needs of caregivers (SCNS-
P&C45)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The number of sessions will be 8 sessions for the intervention group, two sessions for one hour each week in groups of 5 people. The subject of the peer support group meetings is based on the needs and interests of caregivers, which will be asked in the first meeting. Caregivers' needs that are raised more frequently and in more groups during the needs assessment session will be given higher priority to be raised in the support sessions and will be planned separately for the next seven sessions. At this stage, support meetings are held based on the importance of using group dynamics during the meetings and not one person riding on the time of the meeting, based on argumentative debate and nominal group techniques, so that every problem that is raised during the support meetings is discussed by all members. The group is placed and all the members have the right to comment and participate in the discussion, and the nurse and peer caregivers are encouraged to express their experiences and comment on the problems, and the caregivers are also asked to think, examine and analyze each other's solutions and methods of adaptation. and try to improve the mentioned solutions and experiences by providing their additional comments. In each meeting, the problem is first prioritized and discussed and experiences are shared according to the needs assessment meeting, then the peers receive feedback from the previous support meetings, and the way the caregivers use the materials mentioned in the previous meetings is questioned, and if new problems arise, These problems are evaluated by the nurse and peer and suggested solutions are provided to them by other caregivers. The community health nurse is present during the meetings and examines and analyzes the experiences and proposed solutions in order to modify and adjust unreasonable methods or dangerous, superstitious, unattainable and troublesome experiences in order to prevent the transmission of harmful experiences and causing losses. and prevent secondary risks, also the nurse records the support sessions so that after the session she can extract the topics of the session and make them available to the participants. Also, the nurse helps the peer in setting up the meeting on time, the order of the meeting, and observing the health protocols for the prevention of covid during the meeting, which peer support includes three dimensions:1- Emotional support: During the course of a person's life, self-confidence is faced with threats that increase doubts about their abilities, social attractiveness, or job performance, having someone to discuss personal problems with is a powerful resource between A person is responsible for dealing with threats to self-confidence, and this task is called emotional support and includes: means of care, encouragement, listening carefully, responding, reassurance, and avoiding advice and criticism.2- Informational support: If a person's problem is not easily solved, he looks for new information to solve it. This support is provided through recommendation mechanisms, suggestions, real words, problem-solving knowledge, and requires access to resources, independent assessment of etiology,

intermittent course of action, and guidance on efficacy.3- Evaluation support: It requires the exchange of information related to self-evaluation and includes expressions that emphasize the appropriateness of feelings, cognition and behaviors. Its mechanism includes motivational aspects such as encouraging to persist in solving the problem, assuring the results of the efforts, helping to tolerate disappointment and optimism in the relationship, and these interactions create future positive expectations (22). In fact, the peer support system is a system of giving and receiving help based on key rules, including respect, responsibility sharing, and mutual empathy on a topic that is useful. The purpose of providing emotional support, information and assessment of the situation by those who were in the same situation before and experienced it. In this study, we use all three types of support, so that every person who needs help in any area will be supported and will be re-evaluated by peers to investigate new problems. In this study, we hold peer support group meetings, and after the meeting, the contents of each meeting will be available to the intervention group through pamphlets and from the platform of virtual space, and they can review the contents of the support meetings, the list of needs and problems. And the interests of the caregivers prepared in the first meeting are updated during the following meetings so that new needs are identified and the programs are updated and modified. In the peer support group, the nurse as a facilitator creates group effectiveness and the main role in holding meetings will be the responsibility of the peers, and the role of the nurse is mostly to correct the informational blind spots of the peers, provide supplementary and needed information to the peers, and increase the peer's ability to establish proper communication. With other caregivers, creating and producing appropriate content in the form of pamphlets and the content of support sessions, paying attention to the guidelines and health protocols regarding the covid disease during the sessions.

Category
Lifestyle

2

Description

Control group: For the participants in Muntasari hospital, who are the control group of the study, nursing training will be conducted according to the approvals of the patient education committee, and none of the participants in the study will be deprived of routine care.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Seventeen Shahrivar Hospital
Full name of responsible person

Dr. Hossein Hosseinpour
Street address
Between 14 and 16 Kuhsangi, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
1111111111
Phone
+98 51 3840 3015
Fax
+98 51 3842 4060
Email
vshahrivar_razavi.hos@tamin.ir
Web page address
<https://vshahrivar-razavi.tamin.ir>

2

Recruitment center

Name of recruitment center
Muntasari Hospital
Full name of responsible person
Dr. Mohsen Ali Akbarian
Street address
Imam Khomeini 25, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
1111111111
Phone
+98 51 3229 1963
Fax
+98 51 3229 1960
Email
Mh.manager@mums.ac.ir
Web page address
<https://moth.mums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Talat Khadivzadeh
Street address
Faculty of Nursing and Midwifery, Doctor's Crossroad, Ibn Sina Street, University of Mashhad, Khorasan Razavi
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone

+98 51 3859 1511
Fax
+98 51 3859 7313
Email
Nms.pr@mums.ac.ir
Web page address
<https://nurse.mums.ac.ir>
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mashhad University of Medical Sciences ,Research assistant
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
Mashhad University of Medical Sciences
Full name of responsible person
Masoud Zare
Position
Academic staff
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
ditors four way
City
mashhad
Province
Razavi Khorasan
Postal code
11111111
Phone
+98 51 3333 3333
Email
naderghenaati@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Masoud Zare
Position

Academic staff
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
doctors four way
City
Mashhad
Province
Razavi Khorasan
Postal code
11111111
Phone
+98 51 1111 1111
Email
zaremd@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Masoud Zare
Position
Academic staff
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Address: Faculty of Nursing and Midwifery, Ibn Sina Street, Doctora Crossroads, University Street, Khorasan Razavi, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Fax
+98 51 3859 7313
Email
zaremd@mums.ac.ir
Web page address
<https://nurse.mums.ac.ir/>

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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