Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Nader Ghenaati
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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

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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 Muntasarih 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

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2

Recruitment center

Name of recruitment center

Muntasarih Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

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Latest degree

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Other areas of specialty/work

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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