Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The efficacy of Internet-based stress management training program on caring burden and perceived stress of hemodialysis caregivers

Protocol summary

Study aim
Evaluation of the efficacy of Internet-based stress management training program on caring burden and perceived stress of hemodialysis caregivers

Design
Superiority clinical trial, randomized controlled trial, using a random blocking allocation that cannot be blinded and sample size will 60 people.

Settings and conduct
The research will be performed in Imam Hossein Hospital and Red Crescent Hemodialysis Center in Shahroud conducted in six webinar sessions. Standard questionnaires of perceived stress, caring burden at the beginning and before the intervention and 14 days later are completed by both intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age above 18 years, Caregiver has the most contact with the patient, Ability to access the Internet and online mass communication software, Six months history of patient care. Exclusion criteria: Acute psychological disorders in caregivers, Neuroleptic medication in caregivers, The presence of a physical disability in the caregiver.

Intervention groups
Intervention group 6 sessions of 35 to 45 minutes will be held in the form of the group video call. The content of support in 3 sessions is related to the field of education related to hemodialysis and in the field of psychological support during 3 sessions, in the form of stress management based on the theoretical basis of Lazarus and Folkman. the control group will receive routine support.

Main outcome variables
Perceived Stress, Caregiver burden

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180728040617N6**
Registration date: **2023-04-17, 1402/01/28**
Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**
Update count: **0**

Registration date
2023-04-17, 1402/01/28

Registrant information
Name
Seyedmohammad Mirhosseini
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 23 3239 3811
Email address
mirhoseinim@shmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The efficacy of Internet-based stress management training program on caring burden and perceived stress of hemodialysis caregivers

Public title
The efficacy of Internet-based stress management training program on caring burden and perceived stress of hemodialysis caregivers
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years Caregiver has the most contact with the patient Ability to access the Internet and online mass communication software Six months history of patient care
Exclusion criteria:
Acute psychological disorders in caregivers Neuroleptic medication in caregivers The presence of a physical disability in the caregiver
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Caregivers will be divided into intervention and control groups by random block allocation using quadruple blocks created by SPSS software version 22. According to the sample size of 60 in the present study, 15 quadruple blocks will be considered. Each caregiver will be randomly assigned to Group A (intervention) or B (control group) in the order determined by the software, and the sampling process will be performed sequentially until sampling is completed. Individuals are assigned to the target group in order of their entry into the study and randomly through randomized blocks.
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 Shahroud University of Medical Sciences
Street address
Shahroud University of Medical Sciences, Tehran St., Shahroud, Iran.
City
Shahroud
Province
Semnan
Postal code
3614773955
Approval date
2023-02-05, 1401/11/16
Ethics committee reference number
IR.SHMU.REC.1401.218

Health conditions studied

1

Description of health condition studied
Chronic kidney disease
ICD-10 code
N18
ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
caregiver burden
Timepoint
At the beginning of the study (before the intervention) and 7 days after intervention.
Method of measurement
Zarit Burden Inventory

2

Description
Perceived Stress
Timepoint
At the beginning of the study (before the intervention) and 7 days after intervention.
Method of measurement
Cohen Perceived Stress Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the intervention group, 6 sessions will be held in the form of participation in a group video call (webinar) in the form of lectures, group discussions, questions and answers, slide shows and clips. Supportive content in the educational field: (hemodialysis education, diet, physical activity) and in the psychological field of the stress management

program according to the theoretical model of stress management by Lazarus and Folkman (1- stress education and factors affecting it 2- support older adults in identifying ineffective and stressful thoughts 3- Providing solutions (problem-oriented and emotion-oriented) in dealing with stress 4- Providing support in applying the support provided in daily life. Data collection tools include demographic information form, Perceived Stress scale (PSS-14) and Zarit Burden Inventory which were administered by all caregivers before the intervention before the first session. (Intervention and Control Group), will be completed. After 7 days from the end of the intervention sessions, the mentioned questionnaires will be completed to assess the effect of the intervention.

Category
Other

2

Description
Control group: They will receive routine support from the treatment center. Supporting contents will be provided to the control group after the intervention.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital

Full name of responsible person
Ramisa Khooban

Street address
Imam Hossein Hospital, Emam St., Shahroud, Iran.

City
Shahroud

Province
Semnan

Postal code
3614773947

Phone
+98 23 3239 5054

Email
ramisa.shargh@gmail.com

2

Recruitment center

Name of recruitment center
Red Crescent Hemodialysis Center

Full name of responsible person
Ramisa Khooban

Street address
22th Bahman St., Shahroud, Iran.

City
Shahroud

Province
Semnan

Postal code
3617645135

Phone
+98 23 3234 7886

Email
ramisa.shargh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Mohammad Hassan Emamian

Street address
Shahroud University of Medical Sciences, Tehran St., Shahroud, Iran.

City
Shahroud

Province
Semnan

Postal code
3614773947

Phone
+98 23 3239 5054

Email
emamian@shmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Seyedmohammad Mirhosseini

Position
Instructor of Nursing

Latest degree
Master

Other areas of specialty/work
Nursery

Street address

Shahroud University of Medical Sciences, Tehran St., Shahroud, Iran.

City
Shahroud

Province
Semnan

Postal code
3614773955

Phone
+98 23 3239 3811

Email
smohammadmh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Ali Abbasi

Position
Assistant professor of nursing

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Shahroud University of Medical Sciences, Tehran St., Shahroud, Iran.

City
Shahroud

Province
Semnan

Postal code
3614773955

Phone
+98 23 3239 3811

Email
abbasi_msn@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Seyedmohammad Mirhosseini

Position
Instructor of Nursing

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Shahroud University of Medical Sciences, Tehran St., Shahroud, Iran.

City
Shahroud

Province
Semnan

Postal code
3614773955

Phone
+98 23 3239 3811

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Some of the caregivers demographic information can be shared after unidentifying individuals. All of the caregivers' perceived stress and caregiver burden assessment information can be shared with caregivers after unidentified individuals.

When the data will become available and for how long
After publishing the article

To whom data/document is available
Project partners

Under which criteria data/document could be used
People who do similar research

From where data/document is obtainable
It will be done by email with the person in charge of the project.

What processes are involved for a request to access data/document
Data is made available to individuals via email.

Comments