

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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)

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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.

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2

Recruitment center

Name of recruitment center

Red Crescent Hemodialysis Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

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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

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Other areas of specialty/work

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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

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