Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Internet- Based Psychoeducational Support on Perceived Stress and Caring Burden in Caregivers of Patients with COVID-19

Protocol summary

Study aim
Investigation effect of Internet-based psychoeducational support on perceived stress and caring burden in caregivers of COVID-19 patients.

Design
Superiority clinical trial, randomized controlled trial, using a random blocking allocation that cannot be blinded and sample size will 70 people.

Settings and conduct
The research will be performed in Shariati Hospital in Mashhad that 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: Caregiver age between 18-60. No psychological disorders in the caregiver. No drug addiction in the caregiver. No hearing or vision impairment in the caregiver. The caregiver should have the most contact with the patient in the post-discharge period. Ability to access the Internet and online mass communication software. Have the minimum ability to use smartphones and social networks. Non-participation in other supportive interventions in the case of Covid-19. The caregiver should not be a member of the health care system. The caregiver is a family member of the patient. Exclusion criteria: Do not participate in the post-test. Absence from more than two sessions in support sessions. The reluctance of the caregiver to participate in the sessions.

Intervention groups
Intervention group 6 sessions of 35 to 45 minutes per day 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 corona 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, Caring Burden

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210109049978N1**
Registration date: **2021-01-13, 1399/10/24**
Registration timing: **prospective**

Last update: **2021-01-13, 1399/10/24**
Update count: **0**

Registration date
2021-01-13, 1399/10/24

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-18, 1399/10/29

Expected recruitment end date
2021-04-20, 1400/01/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Internet- Based Psychoeducational Support on Perceived Stress and Caring Burden in Caregivers of Patients with COVID-19

Public title

Effect of Internet- Based Psychoeducational Support on Perceived Stress and Caring Burden in Caregivers of Patients with COVID-19

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Caregiver age between 18-60. No psychological disorders in the caregiver. No drug addiction in the caregiver. No hearing or vision impairment in the caregiver. The caregiver should have the most contact with the patient in the post-discharge period. Ability to access the Internet and online mass communication software. Have the minimum ability to use smartphones and social networks. Non-participation in other supportive interventions in the case of Covid-19. The caregiver should not be a member of the health care system (such as doctors, nurses, midwives, etc.). The caregiver is a family member of the patient.

Exclusion criteria:

Do not participate in the post-test. Absence from more than two sessions in support sessions. The reluctance of caregiver in participate in the sessions.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be divided into intervention and control groups by random block allocation using quadruple blocks created by SPSS software version 24. According to the sample size of 70 in the present study, 18 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 Mashhad University of Medical Sciences

Street address

School of Nursing and Midwifery, Ibn Sina St.University St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2020-10-06, 1399/07/15

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.051

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus not identified

Primary outcomes

1

Description

Perceived Stress

Timepoint

At the beginning of the study (before the intervention) and 14 days later.

Method of measurement

Cohen Perceived Stress Scale

2

Description

Caring Burden

Timepoint

At the beginning of the study (before the intervention) and 14 days later.

Method of measurement

Zarit Burden Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, 6 sessions of 35 to 45 minutes per day will be held in the form of group video call (webinar) which will be held in the form of lectures, group discussions, questions and answers, slide shows and clips. Supportive content in the field of education: (Introduction of Covid-19, personal protective equipment, providing care for patient with COVID-19 at home after discharge, nutrition management during COVID-19 crisis, providing care for the elderly, children during the COVID-19 crisis, principles of infection control and Disinfection, warning signs of the disease in those around and the patient in the recovery period, the patient taking medications) and in the psychological field of stress management program according to the theoretical model of stress management Lazarus and Folkman (1- Stress education and its effective factors 2- Supporting caregivers in identifying Stressful dysfunctional thoughts 3- Providing coping strategies (problem-oriented and emotion-oriented) to deal with stress 4- Providing support in applying the support provided in daily life and patient care). Data collection tools included demographic information form, Cohen Standard Perceived Stress Questionnaire (PSS-14) and Zarit Burden Inventory Questionnaire (ZBI) which on the first day after discharge, before the first session in the intervention group by all caregivers (Intervention and Control Group) will be completed online. After 14 days of completing the questionnaires, the mentioned questionnaires will be completed to measure the effectiveness of the intervention on the web.

Category

Other

2

Description

Control group: They use the routine education of the medical center. Supporting contents will be provided to the control group after the intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Saeed Vaghee

Street address

Shariati Hospital, Imam Reza1 St, End Vakil Abad Blvd, dilemma Torghabeh and Shandiz, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Saeed Vaghee

Position

Assistant Professor of Nursing, Faculty member of Mashhad University of Medical Sciences

Latest degree
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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Some of the caregivers' demographic information can be shared after unidentifying individuals. All of the perceived stress and caring 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 and defending the dissertation
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