

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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

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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreyshi building, Daneshgah street, Mashhad

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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

Master

Other areas of specialty/work

Nursery

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Bachelor

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Saeed Vaghee

PositionAssistant Professor of Nursing, Faculty member of
Mashhad University of Medical Sciences**Latest degree**

Master

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Seyedmohammad Mirhosseini

Position

MSc Student in nursing

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 FormUndecided - 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/documentSome 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 obtainableIt 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