

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of family-centered education on stress and anxiety of COVID-19 patients' caregivers

Protocol summary

Study aim

Determining the effect of family-centered education on stress and anxiety in caregivers of patients with COVID-19

Design

Study with a control group, community-based and pragmatic, with a parallel group, without blinding, randomized so that patients admitted on even days of the week to the experimental group and patients admitted on odd days to the group controls will be assigned.

Settings and conduct

Available sampling is performed in Behloul Hospital in Gonabad. In the intervention group, on the first and second days of hospitalization, caregivers will be trained on Covid disease, common symptoms, treatment and routes of transmission, and prevention methods. On the third and fourth days, caregivers are educated about post-discharge care and an educational pamphlet is given. Training sessions will be held for 30 minutes during the patient's hospitalization. The control group will conduct routine. At the end of the fourth day, DASS questionnaires will be completed again for groups.

Participants/Inclusion and exclusion criteria

Patient inclusion criteria: Diagnosis of COVID-19. Caregiver conditions: be a first-degree member of the family and the main caregiver of the patient; no history of illness and mental disorders; education at least the end of primary school; Lack of health jobs; no simultaneous care of another person; no hearing problems; age 18 to 70 years old; no family history of death due to COVID-19. Patient discharge criteria: death of the patient during the study, discharge of the patient less than 4 days. Exclusion criteria caregiver: unwillingness to continue cooperation; changing the patient's caregiver; getting sick with Covid-19.

Intervention groups

intervention group, a training program is performed for 4 days and for 30 minutes every day for patients'

caregivers. control group, patients' caregivers will receive routine manner.

Main outcome variables

Stress and anxiety levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210202050219N1**

Registration date: **2021-04-08, 1400/01/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-08, 1400/01/19**

Update count: **0**

Registration date

2021-04-08, 1400/01/19

Registrant information

Name

Mohamad jamal Tayarani darbandi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3623 8747

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-centered education on stress and anxiety of COVID-19 patients' caregivers

Public title

Investigating the effect of education on stress and anxiety of COVID-19 patients' caregivers

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

A primary family member and primary caregiver of patients admitted to the infectious diseases ward No history of illness and mental disorders based on the patient's history and self-declaration Education at least the end of elementary school Lack of health jobs Not taking care of another person at the same time Have no hearing (full sitting despite the use of assistive devices) and visual (inability to read the newspaper at a distance of 30 cm with or without glasses) problems Being in the age range of 18 to 70 years old No family history of death due to COVID-19

Exclusion criteria:

Reluctance to continue cooperation Change of person accompanying the patient (main caregiver) Infection (main caregiver) of COVID-19 disease

AgeFrom **18 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **25****Randomization (investigator's opinion)**

Randomized

Randomization description

In this way, patients who are admitted on even days of the week will be assigned to the experimental group and patients who are admitted on odd days of the week will be assigned to the control group.

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 Gonabad University of Medical Sciences

Street address

Medical University of Gonabad, Imam Khomeini Avenue

City

Gonabad

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Razavi Khorasan

Postal code

9184113111

Approval date

2021-02-09, 1399/11/21

Ethics committee reference number

IR.GMU.REC.1399.118

Health conditions studied**1****Description of health condition studied**

Stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

2**Description of health condition studied**

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

Stress score in the DASS questionnaire

Timepoint

Measurement of stress score at the beginning of the study (before the intervention) and day 4 after the intervention

Method of measurement

DASS questionnaire

2**Description**

Anxiety score in the DASS questionnaire

Timepoint

Measurement of anxiety score at the beginning of the study (before the intervention) and day 4 after the

intervention
Method of measurement
DASS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the family-centered training program will be implemented individually for caregivers of patients with COVID-19. The family-centered training program begins at the beginning of the patient's hospitalization. The researcher will stay with the family and answer their questions, concerns and feelings. On the first and second days of hospitalization, caregivers will be taught about the nature of COVID-19 disease, common symptoms, treatment, and ways of transmitting the disease, especially prevention methods when dealing with a patient. Third and fourth days in connection with post-discharge care, which includes patient care during quarantine, proper use of personal protection for the patient and family members, how to disinfect the environment, patient clothes and dishes, and proper diet for the patient and family members, Danger signs and the patient's return to the hospital, the caregivers are trained and the educational pamphlet prepared in this field is delivered to the patients.

Category

Other

2

Description

Control group: it will be treated according to routine and the educational intervention mentioned in the research will not be performed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Behloul Gonabadi Hospital

Full name of responsible person

Reza Nouri

Street address

Allameh Behoul Gonabadi Hospital, Parstar Blvd.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Shahla Khosravan

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Mohammad Jamal tayarani Darbandi

Position

masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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