

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The Effect of Tele-Nursing on Caregiver Burden in Family Caregivers and Self-Efficacy in Patients With Covid-19 After Discharge From Hospitals

Protocol summary

Study aim

Determining The Effect of Tele-Nursing on Caregiver Burden in Family Caregivers and Self-Efficacy in Patients With COVID-19

Design

This is a randomized clinical trial study that will be performed on 60 patients with covid-19 and patient caregivers.

Settings and conduct

Using easily available sampling, we sample all patients with covid-19 and their family caregivers who have been admitted and discharged in hospitals affiliated to Sabzevar University of Medical Sciences. Samples are randomly divided into experimental and control groups based on permutation blocks. demographic characteristic questionnaire, Caregiver Burden and self-efficacy before and after one month of intervention online To be completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Lack of Clear Mental and Cognitive Impairment and Severe Mood-Emotional Disorder Patients in Live in House Quarantine Failure To Participate in The Empowerment Program Have a Diagnosis of Covid-19 (positive PCR test) Having a home phone or cell phone Be careful Exclusion criteria: The Patient's Unwillingness To Participate in The Study

Intervention groups

In the Intervention Group, a 2-3 Hour Training Session is Held Under The Title of one-day Training Workshop Through Multimedia Software (Audio, Video, Image) and Related Platforms Including WhatsApp, Imo and Telegram, for Patients and Caregivers of the Same Patients. After That, in the Intervention group, Telephone Follow-up for one Month Will Be Done Daily in the First Two Weeks and Two Days in the Second Two Weeks. For the control group, only routine hospital care.

Main outcome variables

Caregiver Burden in Family Caregivers and Self-Efficacy in Patients With COVID-19

General information

Reason for update

Acronym

Covid-19

IRCT registration information

IRCT registration number: **IRCT20210111050011N1**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

Ahmad Rajab Dizavandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3212 7476

Email address

ahmad.r.dizavandi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-04-09, 1400/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Tele-Nursing on Caregiver Burden in Family Caregivers and Self-Efficacy in Patients With Covid-19 After Discharge From Hospitals

Public title

The Effect of Tele-Nursing on Caregiver Burden in Family Caregivers and Self-Efficacy in Patients With Covid-19

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having informed consent to participate in the study Age Over 30 Years and Maximum 60 Years No Hearing Or Vision Disorders (Deaf And Dumb) Lack of Clear Mental and Cognitive Impairment and Severe Mood-Emotional Disorder That Prevents Effective Communication No Event Or a Stressful Event in The Last 6 Months for the Patient Speak Persian or Understand Persian (Or Have a Companion Who Dominate in Persian) Be Able To Read or Write (Or Have a Companion Him Literacy For Reading and Writing) Patients living with Family Patients in Live in House Quarantine Failure To Participate in The Empowerment Program Have a Diagnosis of Covid-19 (positive PCR test) Having a Home Phone or Cell Phone Be Careful Have Experienced the Same Conditions for Covid-19 Disease.

Exclusion criteria:

The Patient's Unwillingness To Participate in The Study

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be selected by available methods and will be randomly assigned to intervention and control groups using random allocation blocks. R Software will be used to get the blocks. The blocks are made up of 4 English letters (A,B,C,D). A , and B will be considered for the intervention group, and other two letters (C, and D) will be considered for the control group. The blocks will be randomly selected in blindfolded manner. Each block will determine the order of entry in the intervention and control groups. Assuming choosing the DABC block means from left hand, first, and fourth, respectively, will be located in the control group, and the second, and third of participants will be located in the intervention group, respectively. Thus, fifteen blocks will be selected to complete the sampling.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is single blind and only the participant and the

statistical consultant are not aware that the participant is in the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Sabzevar University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Campus of the University of Medical Sciences, above the Memorial of the Unknown Martyrs, Blvd of Nuclear Martyrs

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Approval date

2021-02-08, 1399/11/20

Ethics committee reference number

IR.MEDSAB.REC.1399.174

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

Coronavirus Disease (COVID-19)

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

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

Caregiver Burden in Family Caregivers'

Timepoint

Before and After one Month of Intervention

Method of measurement

Novak and Guest Caregiver Burden Questionnaire (1989)

2**Description**

Self-Efficacy of Patients With Covid-19

Timepoint

Before and After one Month of Intervention

Method of measurement

Prevention, Recognition and Home-Management Self-Efficacy Scale (COVID-19-SES)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the Intervention Group, a 2-3 Hour Training Session is Held Under The Title of one-day Training Workshop Through Multimedia Software (Audio, Video, Image) and Related Platforms Including WhatsApp, Imo and Telegram, for Patients and Caregivers of the Same Patients. And training on the disease and ways to prevent its transmission, attention to quarantine time, location (features of the quarantine room, disinfection of the quarantine room, patient areas such as bathrooms and toilets), social communication, diet and medication In quarantine, psychological issues (psychological strategies for stress management), having a healthy lifestyle, sleeping and resting in quarantine, management of outpatient care (weakness and lethargy, fever and body aches, loss of sense of smell, nausea and vomiting, diarrhea, Ventilation, adequate nutrition, adequate fluids, providing minimum facilities for psychosocial support) are provided to the patient and caregiver. After That, in the Intervention group, Telephone Follow-up Will Be Done Daily for one Month in the First Two Weeks and Two Days in the Second Two Weeks. An Agreement is Reached Regarding Follow-up Times and Calls, and The Contact Number of The Researcher and WhatsApp, Imo, Telegram and SMS Media are Provided to the Participants so that They can Communicate and Ask their Questions Whenever Necessary. Depending on the Condition of the Caregiver and the Patient, and Depending on Which Stage of The Disease the Patient is in, There is Training and Related Care Appropriate to that Stage of the Disease, and If Necessary, the Patient is Referred to an Infectious Disease Specialist. Remote Nursing Recommendations are also Given to Prevent Infection Transmission, Patient Recovery, and Outpatient Problems.

Category

Rehabilitation

2**Description**

Control group: Only Routine Hospital Care Will be Provided. The ward Nurse Provides The Necessary Training Related to Infection Control, Medication Use, Go to The Hospital If The Patient's Condition Worsens and Visit Again.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vasei Educational and Medical Center

Full name of responsible person

Abolfazl Shakiba

Street address

Vasei Hospital, Tohid Shahr Blvd, Sabzevar

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshteh Ghorat

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Vice Chancellor for Research and Technology, Campus of the University of Medical Sciences, above the Memorial of the Unknown Martyrs, Boulevard of Nuclear Martyrs

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Email

vc.Research@medsab.ac.ir

Web page address

<http://vcresearch.medsab.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sabzevar 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

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

Sabzevar University of Medical Sciences

Full name of responsible person

Ahmad Rajab Dizavandi

Position

Master Student of Internal Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Campus of the University of Medical Sciences, above the Memorial of the Unknown Martyrs, Blvd of Nuclear Martyrs

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Contact**Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Ahmad Rajab Dizavandi

Position

Master Student of Internal Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

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

Sabzevar University of Medical Sciences

Full name of responsible person

Mostafa Rad

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Campus of the University of Medical Sciences, above the Memorial of the Unknown Martyrs, Blvd of Nuclear Martyrs

City**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

For More Security of Participants' Data

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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