Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617747431
Phone
+98 51 4465 1300
Fax
+98 51 4465 3861
Email
abolfazlshakiba1360@gmail.com
Web page address
https://www.medsab.ac.ir/index.aspx?siteid=1&pageid=158

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Fereshteh Ghorat
Street address
Vice Chancellor for Research and Technology, Campus of the University of Medical Sciences, above the Memorial of the Unknown Martyrs, Boulevard of Nuclear Martyrs
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112- 96179131
Phone
+98 51 4401 8101
Fax
+98 51 4401 8102
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

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
City
Sabzevar
Province
Razavi Khorasan
Postal code
9157863346
Phone
+98 51 3212 7476
Email
ahmad.r.dizavandi@gmail.com

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
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 4401 8308
Email
mostafarad633@yahoo.com

Person responsible for updating data

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
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 3212 7476
Email
ahmad.r.dizavandi@gmail.com

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