Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of the web- based communication between nurse and family member on perceived stress of family member of suspected and affected patients with COVID-19

Protocol summary

Study aim
Determining the effectiveness of web-based communication between nurse and family member on the perceived stress of family member of a patient with COVID-19

Design
Clinical trial with control group, with parallel groups, single blind , randomized, phase 3 Clinical trial, 74 family members

Settings and conduct
The study is being conducted in two ICU of Imam Hossein Hospital in Shahroud, where patients have been hospitalized since the beginning of the COVID-19 outbreak.

Participants/Inclusion and exclusion criteria
Patient Inclusion Criteria: - Patients with COVID-19 whose disease has been diagnosed by lung CT scan and positive PCR and are undergoing standard treatment. - Patients who are hospitalized in the intensive care unit due to the severity of the disease. Family Inclusion Criteria: - A family member who has a relative or causal relationship with the patient. - Have web literacy and be able to communicate via virtual and participate in the web communication program. - The family member is not a member of the treatment team.

Intervention groups
In the intervention group, web-based communication is established between the nurse and the family member. The content of the intervention includes daily contact by the researcher's telephone with a family member. After communication, information is provided about the patient's vital signs, the patient's respiratory status, level of consciousness, the patient's nutritional pattern and no need for physical presence of the family in the hospital.These calls are made in four days and include one call per day for 10-15 minutes. The control group receive all routine medical and care interventions except web-based communication with the family member.

Main outcome variables
Perceived stress on family members

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200223046586N2**
Registration date: **2020-05-30, 1399/03/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-30, 1399/03/10**
Update count: **0**

Registration date
2020-05-30, 1399/03/10

Registrant information

Name
Esmail Shariati

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
2020-05-18, 1399/02/29

Expected recruitment end date
2020-06-20, 1399/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the web- based communication between nurse and family member on perceived stress of family member of suspected and affected patients with COVID-19

Public title
web- based communication between nurse and family member
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Satisfaction to participate in research Patients with COVID-19 whose disease has been diagnosed by lung CT scan and positive PCR and are undergoing standard treatment. Patients who are hospitalized in the Intensive Care Unit due to the severity of the disease. Having a family member (relative or causal) with web literacy and being able to communicate virtually and participate in a web-based communication program. The family member is not a member of the treatment team.
Exclusion criteria:
Having hearing and speech problems The family member has psychological problems based on self-expression Patients who are in the control group and in any way provided with the possibility of web contact during the hospital stay Severe stress in the family over the past month except for a patient with Covid-19, such as death of other family members
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
The sequence of random allocation and the list of blocks will be obtained by the statistical consultant with the help of software. The website https://www.sealedenvelope.com is a useful site for generating random sequences for block type randomization. This site is designed in such a way that there is no limit on the number of groups for random allocation. Volume block method 4 is used to create random allocation sequences. According to the total number of samples required for the study, which is 74 patients (37 patients in the intervention group (A) and 37 patients in the control group (B)), 19 blocks with a volume of four includes two groups A and B will be randomly selected using the software, such as (ABAB) ، (BBAB)، (AABB)، (ABBA)، (BAAB .....(Then 74 pockets (37 pockets containing paper containing A and 37 pockets containing B) will be prepared based on sample size. According to a list of blocks, a trained person outside of the research team will be set the row of pockets. After admission of each patient to the intensive care unit, will be given a pocket and assigned to Group A (intervention) or B (control group), and the sample process will be performed sequentially until the end of completion of sample size.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the study, it is not possible to blind participants and implement the intervention. However, demographic information and stress assessment questionnaires are performed at the beginning of the intervention by a trained nurse outside the research team. The data are given to the statistician for analysis. The data collector and analyst are not aware of how individuals are assigned to groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shahroud University of Medical Science
Street address
Shahroud, Seventh Tir Square, Shahroud University of Medical Sciences and Health Services, Vice Chancellor for Research and Technology
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Province
Semnan
Postal code
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Approval date
2020-05-09, 1399/02/20
Ethics committee reference number
IR.SHMU.REC.1399.027

Health conditions studied

1

Description of health condition studied
Covid -19

ICD-10 code
U07.2
ICD-10 code description
COVID-19, virus not identified

Primary outcomes

1

Description
Perceived Stress
Timepoint
At the beginning of the study (before the start of the intervention) and 4 days later
Method of measurement
Perceived Stress Scale (PSS-14). A 14-item questionnaire in the 5-point Likert range between 0 and 4. The lowest score is zero and the highest score is 56, and getting a higher average score indicates more perceived stress.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Due to the absence of the family in the hospital, to access them, with the permission of the hospital manager, the telephone number of the family member of each patient will be asked and after calling the family and explaining the goals of the study and obtaining oral and written consent, A family with inclusion criteria will be included in the study. Then, the number of mobile phone improved enough to install Soroush or WhatsApp application will be asked from each family member so that this phone number can be contacted during the intervention period. Then, before the beginning of the intervention, a demographic information questionnaire and a perceived stress questionnaire (PSS-14) will be completed by a family member (due to hospital conditions and the impossibility of the family attending the hospital, the online questionnaire will be sent to family members). Patient demographic information will be obtained from patient's medical record. Next, the web-based communication between the nurse and the family member will be done. Intervention content includes daily web contact by the researcher's family member. After communication, information is given about the status of vital signs, respiratory status, level of alertness, patient nutrition pattern, and no need for physical presence of the family in the hospital. Calls will be made within four days and include one call per day for 10-15 minutes. During the entire intervention period, four calls will be made during the patient's hospitalization in the intensive care unit. The contact time will be determined each day based on coordination with the family member. The questionnaire (PSS-14) then will be completed by the family on the intervention day. For the family member, the questionnaire will be sent online. Then, after collecting the questionnaires, the information will be analyzed through SPSS software.
Category
Other

2

Description
Control group: All routine medical treatment and care interventions, except web-based communication with the family, will be performed, and the PSS-14 questionnaire will be completed twice by the family member (at the beginning of the study and four days later).
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital affiliated to Shahroud University of Medical Sciences
Full name of responsible person
Esmail Shariati
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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

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Esmail Shariati

Position

Master of Science in Nursing, Shahroud University of Medical Sciences

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the demographic information of the patient and family member can be shared after identifying

individuals. All information related to measuring the perceived stress in family member can be shared after identifying people.

When the data will become available and for how long

Access period starts from May 2020

To whom data/document is available

Researchers and students of academic and scientific institutions

Under which criteria data/document could be used

data for correlational studies

From where data/document is obtainable

shariati.esmail@yahoo.com

What processes are involved for a request to access data/document

Clear explanation of the reason for the need to access the data and submit the data after two weeks

Comments