Clinical Trial Protocol
Iranian Registry of Clinical Trials
01 Jun 2021

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
Country
Iran (Islamic Republic of)
Phone
+98 23 3234 2000
Email address
shariati@shmu.ac.ir

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), (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

**City**
Shahroud

**Province**
Semnan

**Postal code**
3614773955

**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 online. Then, after collecting the questionnaires, the information will be analyzed through SPSS software.

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
Street address
No. 63. Alley. 8. Foroughi Street. Shahroud
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Email
shariati.esmail@yahoo.com

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mohammad Hassan Emanian
Street address
Shahroud, 7th of Tir Square, Shahroud University of Medical Sciences and Health Services, Vice Chancellor for Research and Technology
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Shahroud
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Semnan
Postal code
۵۵۹۳۷۷۴۱۶۳
Phone
+98 23 3239 6714
Email
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
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   Province
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Person responsible for scientific inquiries
Contact
   Name of organization / entity
Shahroud University of Medical Sciences
   Full name of responsible person
Hossein Ebrahimi
   Position
Faculty Member, Shahroud University of Medical Sciences
   Latest degree
Ph.D.
   Other areas of specialty/work
Nursery

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**