Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Aug 2026

The effect of the Video communication between patient and family member on hospital anxiety and depression of of affected patients with COVID-19 and perceived stress of family member

Protocol summary

Study aim
Determining the effectiveness of the Video communication between patient and family member on hospital anxiety and depression of affected patients with COVID-19 and perceived stress of family member

Design
A clinical trial with a control group, with parallel groups, single blind , on 80 patients and 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. The study was conducted single blind and the data analyzer was not aware of how patients were divided. block with size of 4 is used to create random allocation sequences. 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).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Suspected and definitively diagnosed COVID-19 patients by positive chest CT scan and PCR / Patients who are hospitalized in the intensive care unit due to the severity of the disease and are not intubated / Has web literacy and is able to communicate via video. Exclusion criteria: A family member is a member of the treatment team / Has hearing and speech problems / Excessive stressful occurrence in the family during the past month other than Covid-19 infection, such as death of members Family

Intervention groups
In the intervention group, the Video communication is established between the patient and the family member. These calls are made in three days and include one call per day for 5-10 minutes. The control group receive all routine medical and care interventions except the Video communication with the family member.

Main outcome variables
The hospital anxiety and depression and perceived stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200223046586N4**
Registration date: **2021-05-24, 1400/03/03**
Registration timing: **prospective**

Last update: **2021-05-24, 1400/03/03**
Update count: **0**

Registration date
2021-05-24, 1400/03/03

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
2021-06-04, 1400/03/14

Expected recruitment end date
2021-08-05, 1400/05/14

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the Video communication between patient and family member on hospital anxiety and depression of of affected patients with COVID-19 and perceived stress of family member

Public title
The Video communication between patient and family member on hospital anxiety and depression and perceived stress of family member
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Suspected and definitive patients with COVID-19 by a specialist through chest CT scan and positive PCR . Patients who are hospitalized in the intensive care unit due to the severity of the disease and are not intubated. Patients who have been hospitalized in the intensive care unit for a maximum of 24 hours. A family member who has a relative or causal relationship with the patient . Have web literacy and be able to communicate via video.
Exclusion criteria:
Be a family member of the treatment team. Have hearing and speech problems. The family member has psychological problems based on self-declaration. Occurrence of severe stress in the family during the past month other than the patient contracting Covid-19, such as death of family members
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **80**
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 80 patients (40 patients in the intervention group (A) and 40 patients in the control group (B)), 20 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 80 pockets (40 pockets containing paper containing A and 40 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 and hospital anxiety and depression 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
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Approval date
2021-05-08, 1400/02/18
Ethics committee reference number
IR.SHMU.REC.1400.035

Health conditions studied

1

Description of health condition studied
Covid-19 Disease
ICD-10 code

U07.2

ICD-10 code description

COVID-19, virus not identified

Primary outcomes

1

Description

Hospital Anxiety and Depression

Timepoint

Before the intervention and 24 hours after the intervention

Method of measurement

Hospital Anxiety and Depression Scale (HADS) containing 14 questions on a 5-point Likert scale

2

Description

Perceived Stress

Timepoint

Before the intervention and 24 hours after the intervention

Method of measurement

Perceived Stress Scale (PSS) containing 14 questions on a 5-point Likert scale

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 starting the intervention, the Demographic Information Questionnaire and the Perceived Stress Questionnaire (PSS-14) are completed by a family member due to the hospital conditions and the impossibility of the family attending the hospital, an online questionnaire is sent to family members. The Hospital Anxiety and Depression Scale is completed by patients. Patient demographic information will be obtained from patient's medical record. Next, the video communication between the patient and the family member will be done. Calls will be made within three days and include one call per day for 5-10 minutes. During the entire intervention period, three 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 questionnaires are then completed again by the family and the patient on the day of the intervention. After collecting the questionnaires, the information will be analyzed through SPSS software.

Category

Behavior

2

Description

Control group: All routine treatment and care interventions except video communication between patient and family member are performed for the control group. In the control group, if a family member contacts the intensive care unit, their questions will be answered and short-term telephone conversations will be provided if the physical condition is favorable. Questionnaires will be used twice at the beginning of the study and 24 hours after the intervention to be completed.

Category

Behavior

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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Full name of responsible person

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
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Full name of responsible person
Esmail Shariati
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

Part of the patient and family member demographic information can be shared after the person is not identified. All information about the patient's anxiety and stress in the family member can be shared after the person is not identified.

When the data will become available and for how long

From the end of August 2021

To whom data/document is available

Researchers / students of health sciences

Under which criteria data/document could be used

A clear explanation of the reason for the need to access the data and provide the data after two weeks

From where data/document is obtainable

See the email address below shariati.esmail@yahoo.com

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

After providing the reason for the need to access the data and send it to the following email, the data will be provided. shariati.esmail@yahoo.com

Comments