

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Evaluation of the effect of scheduled online video meeting on anxiety, stress and depression of patients admitted with Quaid 19

#### Protocol summary

##### Study aim

The effect of scheduled online video meeting on anxiety, stress and depression in patients with COVID 19

##### Design

Clinical trial with control group, with parallel groups, double blind, randomized, with a sample size of 30

##### Settings and conduct

This study was performed on patients with COVID-19 who were admitted to Torbat Heydariyeh Hospital on the 9 day. On the first and second day of hospitalization in the COVID-19 support ward, video calls in the morning, evening and night shifts between the patient and the patient's family are made by the researcher's tablet in the ward and the patient's family's smartphone at home.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: COVID-19 disease and be sick on the first or second day of hospitalization. Conditions of non-entry: do not want to continue participating in the research and the impossibility of video communication more than 2 times in the intervention group.

##### Intervention groups

In the intervention group, on the first and second day of hospitalization in COVID-19 support ward, video call in morning, evening and night shifts and each shift once for 10-15 minutes between the patient and the patient's family by the researcher's tablet in the ward and the family smartphone. The patient is performed at home. In the control group, communication with the patient's family is done by telephone and at times when the patient's condition and condition of the ward allow. Also, in both control and intervention groups, when the ward and patient conditions allow, the visitors can visit their patient in accordance with the principles of personal protection.

##### Main outcome variables

Stress, anxiety and depression

#### General information

##### Reason for update

End of sampling

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180429039463N4**

Registration date: **2022-04-10, 1401/01/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-08-13, 1401/05/22**

Update count: **1**

##### Registration date

2022-04-10, 1401/01/21

##### Registrant information

##### Name

mohammad namazinia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5222 5280

##### Email address

namazinm951@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-04, 1401/01/15

##### Expected recruitment end date

2022-06-20, 1401/03/30

##### Actual recruitment start date

2022-04-04, 1401/01/15

##### Actual recruitment end date

2022-08-11, 1401/05/20

##### Trial completion date

2022-08-11, 1401/05/20

## Scientific title

Evaluation of the effect of scheduled online video meeting on anxiety, stress and depression of patients admitted with Quaid 19

## Public title

Evaluation of the effect of scheduled online video meeting on anxiety, stress and depression of patients admitted with Quaid 19

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having informed consent of patients to participate in the study Patient consciousness Ability to communicate verbally No history of known anxiety and depression problems Hospitalization with definitive diagnosis of Covid-19 for the first time Having a smartphone connected to the Internet by the patient's family The first or second day of hospitalization

### Exclusion criteria:

Patients whose hemodynamic status is unstable Loss of consciousness Reluctance to continue cooperation in research The patient needs vital measures such as intubation Impossibility of video communication more than 2 times in the intervention group

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **30**

Actual sample size reached: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Dividing people into two groups randomly will be used by the random permutation block method. In this way, using blocks with two treatments and a table of random numbers, individuals were assigned to two groups of control and intervention. Then, the personal information questionnaire in both intervention and control groups is completed through interviews. This questionnaire includes information about personal characteristics and medical records (age, sex, type of disease, etc.).

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, participants and outcome assessors did not know whether participants were in the control or intervention 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 Torbat Heydariyeh University of Medical Sciences

##### Street address

Torbat Heydariyeh University of Medical Sciences, Razi St., Torbat Heydariyeh, Iran

##### City

Torbat Heydariyeh

##### Province

Razavi Khorasan

##### Postal code

9519633787

#### Approval date

2021-12-27, 1400/10/06

#### Ethics committee reference number

IR.THUMS.REC.1400.040

## Health conditions studied

### 1

#### Description of health condition studied

Coronavirus disease

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Depression

#### Timepoint

Depression is measured once at the time of admission and the second time 48 hours after admission.

#### Method of measurement

Depression is measured by Depression Anxiety and Stress Scales (DASS-21)

### 2

#### Description

Stress

#### Timepoint

Stress is measured once at the time of admission and the second time 48 hours after admission.

#### Method of measurement

Stress is measured by Depression Anxiety and Stress Scales (DASS-21)

### 3

#### **Description**

Anxiety

#### **Timepoint**

Anxiety is measured once at the time of admission and the second time 48 hours after admission.

#### **Method of measurement**

Anxiety is measured by Depression Anxiety and Stress Scales (DASS-21)

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: In the intervention group, during a face-to-face meeting of 10-15 minutes, the researcher gives the necessary training on the type of study and how to connect to the software and make video calls and visiting hours to the patient and his family. On the first and second day of hospitalization in Covid-19 support ward, video call in morning, evening and night shifts and each shift once for 10-15 minutes between the patient and the patient's family by the researcher's tablet in the ward and the patient's family's smartphone at home Done. Video calling is done using IMO software and at times when the patient's condition and ward condition allow. To avoid disturbing other patients, a handsfree is used to communicate between the patient and the family. Video communication is done when the patient is awake, as well as outside the time of nursing care and doctor visits.

#### **Category**

N/A

#### 2

#### **Description**

Control group: In the control group, communication with the patient's family is done by telephone and at times when the patient's condition and condition of the ward allow. Also, in both control and intervention groups, when the ward and patient conditions allow, the visitors can visit their patient in accordance with the principles of personal protection.

#### **Category**

N/A

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Nohome day Hospital, Torbat Heydariyeh University of Medical Sciences

##### **Full name of responsible person**

Mohammad Namazinia

#### **Street address**

Torbat Heydariyeh University of Medical Sciences Building., Razi St., Ferdawsi St.

#### **City**

Torbat Heydariyeh

#### **Province**

Razavi Khorasan

#### **Postal code**

95195481\$6

#### **Phone**

+98 51 5222 6014

#### **Email**

mnamazi99@gmail.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Torbate-Heidaria University of Medical Sciences

##### **Full name of responsible person**

Dr. Mohammad Reza Rezaei Manesh

##### **Street address**

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mnamazi99@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Torbate-Heidaria 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**

Torbate-Heidaria University of Medical Sciences

##### **Full name of responsible person**

Mohammad Namazinia

**Position**

Member of the faculty of Torbat Heydariyeh University of Medical Sciences

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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Torbat Heydariyeh University of Medical Sciences Building., Razi St., Ferdawsi St

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Mohammad Namazinia

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**Postal code**

95169-33787

**Phone**

+98 51 5222 6013

**Email**

mnamazi99@gmail.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Torbate-Heidaria University of Medical Sciences

**Full name of responsible person**

## 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**

Yes - There is 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**

Information about the main consequence after being unidentified will be shared.

**When the data will become available and for how long**

Start the access period 6 months after Publish results

**To whom data/document is available**

Everyone

**Under which criteria data/document could be used**

The results obtained in this study can be used without restriction by researchers.

**From where data/document is obtainable**

Referring to Torbat Heidarieh Nursing and Midwifery Faculty

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

After sending the email to the person responsible for the response process begins.

**Comments**