

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing of the Effect of Supportive Educative Program with Routine educative program on Stress, Anxiety, Depression and Satisfaction of Patients With COVID-19 Admitted to COVID units

#### Protocol summary

##### Study aim

Effect of Supportive Educative Program on Stress, Anxiety, Depression and Satisfaction of Patients with COVID-19

##### Design

Clinical trial with control group with parallel groups without blinding with random assignment of samples to groups that will be performed on 60 hospitalized patients with definit diagnosis of COVID-19, Random allocation is done using a random sequence generated by the randomization site (at [www.randomization.com](http://www.randomization.com)).

##### Settings and conduct

This study will be performed on 60 patients with COVID-19 referring to the emergency departments of COVID hospitals in Najaf. No blinding will be performed in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Positive COVID PCR test; with p/f ratio < 200; complete awareness. Non inclusion Criteria: history of mental disorder; previous history of COVID-19; history of using psychotropic drugs and Narcotics

##### Intervention groups

Intervention group: expressing empathy with patient and focusing on his concerns at the beginning of the patient's awareness of the diagnosis of COVID-19, Provide the patient with a comprehensive pamphlet based on the educational needs of patients with COVID 19 in need of hospitalization, identifying the patient's trusted companion, and giving him or her a contact number to make telephone and video calls. Also the researcher will answer the concerns and questions that have made for the patient during the hospitalization period. Control group: They receive the usual care and training of Najaf hospitals

##### Main outcome variables

Depression, anxiety and stress; Patient satisfaction with the quality of care

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140625018231N1**

Registration date: **2021-11-05, 1400/08/14**

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

Last update: **2021-11-05, 1400/08/14**

Update count: **0**

##### Registration date

2021-11-05, 1400/08/14

##### Registrant information

##### Name

**Name of organization / entity**

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1859 1511

##### Email address

[hajiabadif@mums.ac.ir](mailto:hajiabadif@mums.ac.ir)

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-22, 1400/07/30

##### Expected recruitment end date

2021-12-21, 1400/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparing of the Effect of Supportive Educative Program with Routine educative program on Stress, Anxiety, Depression and Satisfaction of Patients With COVID-19 Admitted to COVID units

## Public title

The Effect of Supportive Educative Program in COVID-19

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Positive COVID-19 PCR test and definit diagnosis of COVID-19 COVID-19 Patient with P/F ratio <200 Definite need to be hospitalized in COVID-19 ward Full awareness and awareness to time and place

### Exclusion criteria:

Having a history of mental disorders Employment in the treatment team Having a previous history of COVID-19 Having a history of using psychotropic drugs and narcotics

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random allocation is done using random sequences generated by the randomization site. It is done by randomization site (with the site address www.randomization.com). To prepare a random sequence using this site, considering that the total sample size is 60 people in two groups of control and intervention, in this site for 2 groups of 30, the number of blocks of size 4 is given to the site and the random sequence will be obtained. To conceal the assignment, this sequence is placed in sealed envelope until each research unit enters the study.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

#### Street address

Nursing and Midwifery Collage, Ebne Sina Ave., Doctora intersection, Daneshgah Ave.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9137913199

### Approval date

2021-06-13, 1400/03/23

### Ethics committee reference number

IR.MUMS.NURSE.REC.1400.028

## Health conditions studied

## 1

### Description of health condition studied

COVID-19

### ICD-10 code

U07.1

### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

## 1

### Description

Level of depression

### Timepoint

immediately after hospitalization, at the end of the first day of hospitalization and 5 days after hospitalization in both control and intervention groups

### Method of measurement

Depression, Anxiety and Stress Questionnaire (DASS)

## 2

### Description

Level of Anxiety

### Timepoint

immediately after hospitalization, at the end of the first day of hospitalization and 5 days after hospitalization in both control and intervention groups

### Method of measurement

Depression, Anxiety and Stress Questionnaire (DASS)

## 3

### Description

Level of Stress

### Timepoint

immediately after hospitalization, at the end of the first day of hospitalization and 5 days after hospitalization in both control and intervention groups

## Method of measurement

Depression, Anxiety and Stress Questionnaire (DASS)

## 4

### Description

Patient satisfaction with the quality of care

### Timepoint

For both intervention and control groups 5 days after hospitalization

### Method of measurement

Patient Satisfaction Questionnaire (PSI) to measure patient satisfaction with the quality of care

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: expressing empathy with patient and focusing on his concerns at the beginning of the patient's awareness of the diagnosis of COVID-19, Provide the patient with a comprehensive pamphlet based on the educational needs of patients with COVID\_19 in need of hospitalization, identifying the patient's trusted companion, and giving him or her a contact number to make telephone and video calls. Also the researcher will answer the concerns and questions that have arisen for the patient during the hospitalization period and provide the required training according to the patient's needs.

### Category

Behavior

## 2

### Description

Control group: No Educative and supportive programs are provided or performed for patients, and nurses and the treatment team spend their time performing treatment measures such as medication, oxygen therapy, and other procedures.

### Category

Behavior

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Emergency wards, ICU and COVID wards of Alhakim hospitals for patients with COVID-19 in Najaf

#### Full name of responsible person

Ali Abd al-Zahra al-Faham

#### Street address

284W + XJF, Najaf, Iraq

#### City

Najaf

### Postal code

3412565737

### Phone

+964 33 780 0107

### Fax

### Email

info@gms-leipzig.com

### Web page address

<https://www.gms-germanmedicalsolutions.com/en/projects/najaf-teaching-hospital-iraq.html>

## 2

### Recruitment center

#### Name of recruitment center

Emergency wards, ICU and COVID wards of Alhayat hospitals for patients with COVID-19 in Najaf

#### Full name of responsible person

Ali Abd al-Zahra al-Faham

#### Street address

Al Hizam Street, Najaf, Iraq

#### City

Najaf

#### Postal code

3412565737

#### Phone

+964 33 780 0107

#### Email

info@gms-leipzig.com

#### Web page address

<https://vymaps.com/IQ/Al-Hayat-Hospital>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Mohsen Tafaghodi Piadeh Gheibi

#### Street address

Mashhad University of Medical Sciences, Daneshgah Ave.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

13944-91388

#### Phone

+98 51 3841 2081

#### Fax

#### Email

presidentoffice@mums.ac.ir

#### Web page address

<https://www.mums.ac.ir/>

### Grant name

### Grant code / Reference number

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

No

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fateme Hajiabadi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Nursing and Midwifery Collage, Ebne Sina Ave.,  
Doctora intersection, Daneshgah Ave.

**City**

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**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Email**

hajiabadif@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fateme Hajiabadi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fateme Hajiabadi

**Position**

Assistant Professore

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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**

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