

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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).

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

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.

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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.,

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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

Nursery

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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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Email

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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