Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 Anxity

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 suppurtive 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 Sceinces, 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., Doctora intersection, Daneshgah Ave.
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Person responsible for scientific inquiries

Contact
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Mashhad University of Medical Sciences
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Fateme Hajiabadi
Position
Assistant Professor
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Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact
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Fateme Hajiabadi
Position
Assistant Professore
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Email
hajiabadif@mums.ac.ir

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