

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Studying of supportive psychotherapy effect on COVID-19 hospitalized patients with depression and anxiety disorders in Karaj Imam Ali hospital

Protocol summary

Study aim

Comparison of the effect of drug intervention alone and drug intervention with supportive psychotherapy on the bed in patients admitted with COVID-19 and suffering from depression or anxiety disorders.

Design

Clinical trial with control group, with parallel, randomized groups, on 102 patients. Block randomization method will be used.

Settings and conduct

The center where this research is done is Imam Ali Hospital in Karaj. The sample population will be divided into 2 groups. Drug intervention is performed in both groups. At the same time, in the case group, psychotherapy intervention is performed as supportive psychotherapy on the patient's bed. Supportive psychotherapy will be such that 3 sessions during the first week and 3 sessions during the second week, interview with the patient will be done and then 1 month after discharge, the patient is re-evaluated by Beck test. The patient's next follow-up will be 3 months after discharge.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years and under 65 years, with SARS-CoV-2 infection, which has been confirmed by PCR test, Have the required score according to the Beck Depression and Anxiety Test ,Have a GCS above 14, Have O2 saturation above 90%, Have proper cooperation, Willingness to participate in the study. Exclusion criteria: Failure to confirm COVID-19 on PCR ,Serious neurological disease or delirium and decreased LOC, Reluctance to participate in research, History of previous untreated psychiatric illness.

Intervention groups

Hospitalized patients with COVID-19 who, according to the Beck Depression and Anxiety Inventory, have 1 or both of these diseases and are divided into 2 groups, 1 group will receive only medication and the other group, in addition to drug intervention, They will receive

supportive psychotherapy intervention.

Main outcome variables

Beck anxiety and depression score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220115053714N1**

Registration date: **2022-01-26, 1400/11/06**

Registration timing: **prospective**

Last update: **2022-01-26, 1400/11/06**

Update count: **0**

Registration date

2022-01-26, 1400/11/06

Registrant information

Name

Bahar Mozaffari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 903 955 4707

Email address

baharmozaffari5@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2022-05-04, 1401/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Studying of supportive psychotherapy effect on COVID-19 hospitalized patients with depression and anxiety disorders in Karaj Imam Ali hospital

Public title
Studying of supportive psychotherapy effect on COVID-19 hospitalized patients with depression and anxiety disorders in Karaj Imam Ali hospital

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients older than 18 years old and younger than 65 years old. Infected by SARS-CoV-2 with a positive PCR test. Earning enough score of Beck depression and Beck anxiety test. GCS score more than 14 O2 saturation more than 90 percent Patients should be cooperative. willing of the patient to enter the study.
Exclusion criteria:
 People without confirmed SARS-CoV-2 PCR test Having a serious neurologic disease or delirium and loss of consciousness. Patients who doesn't want to enter the study. Having a history of a serious uncontrol psychological condition.

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: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be in blocked randomization and each group will get 2 blocks.

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 Alborz University of Medical Sciences

Street address

Alborz university of medical sciences, West Buali Ave., Nabovvat Blvd., Karaj, Iran.

City

Karaj

Province

Alborz

Postal code

1111111111

Approval date

2022-01-01, 1400/10/11

Ethics committee reference number

IR.ABZUMS.REC.1400.277

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

2

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Depression Beck test score

Timepoint

At the beginning of the study, one month after discharge and three months after discharge

Method of measurement

Beck depression questionnaire - Beck anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The sample population will be divided into two groups and both groups are suffering from depression and anxiety. Drug intervention will be

performed in both groups. At the same time, in the intervention group, psychotherapy intervention is performed as supportive psychotherapy on the patient's bedside and his education. Supportive psychotherapy by a two-member team of psychotherapists and psychotherapists will be such that three sessions during the first week and three sessions during the second week, visits and interviews with the patient and then one month after discharge, the patient by phone to The clinic is invited and re-evaluated by a test back. The patient's next follow-up will be three months after discharge, and for the third time, an evaluation will be performed at this visit.

Category

Rehabilitation

2

Description

Control group: They will only receive medication. The drug used is citalopram from the SSRI family, which is effective in both depression and anxiety.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali hospital

Full name of responsible person

Dr. Atefeh Zandifar

Street address

Emam Ali hospital, Valieasr Blvd., Karaj, Iran

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3154686695

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr. Hatam Goodini

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Deputy of Research and Technology, Saffarian Alley, Golshahr Blvd., Karaj, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Dr. Atefeh Zandifar

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available