

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of cognitive-behavioral crisis intervention package on improving COVID-19 fear symptoms, improving quality of life and improving mental health in patients with corona

Protocol summary

Study aim

The effectiveness of Cognitive-Behavioral Crisis Intervention Package on COVID-19 Fear Symptoms, Improving Quality of Life and Improving Mental Health in Corona Patients

Design

Clinical trial with control group

Settings and conduct

Imam Khomeini, Ziaian and Masih Daneshvari hospitals

Participants/Inclusion and exclusion criteria

Being in the age range of 18 to 60 years old; diagnosis of corona and person to be in the recovery period after drug treatment; tendency to participate in the project.

Intervention groups

8-session Cognitive-Behavioral Crisis Intervention Package

Main outcome variables

Psychological recovery of patients with COVID19

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200509047360N1**

Registration date: **2020-05-16, 1399/02/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-16, 1399/02/27**

Update count: **0**

Registration date

2020-05-16, 1399/02/27

Registrant information

Name

Seyyed Salman Alavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-03, 1399/02/14

Expected recruitment end date

2020-06-03, 1399/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive-behavioral crisis intervention package on improving COVID-19 fear symptoms, improving quality of life and improving mental health in patients with corona

Public title

The effect of cognitive-behavioral intervention on improving COVID-19 fear symptoms, improving quality of life and improving mental health in patients with corona

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being in the age range of 18 to 70 years old Diagnosis of corona and person is in recovery period after drug treatment Desire to participate in the project

Exclusion criteria:

Severe physical problems or visible organ defects
Patients with major depressive disorder, psychotic disorder, or major psychiatric disorder are not included in the study, and primary medication is given to them.
Leaving more than two treatment sessions or unwillingness or requesting to leave the project at the request of the candidate

Age

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

First, a list of members of patients with COVID-19 who are in the recovery phase is prepared. An interview and a demographic information questionnaire are obtained. The sample group (60 people) is then randomly divided into experimental and control groups based on a random number table.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

Has a crisis intervention package

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Keshavarz Boulevard - Tehran University of Medical Sciences Headquarters

City

Tehran

Province

Tehran

Postal code

1333795914

Approval date

2020-06-03, 1399/03/14

Ethics committee reference number

IR.TUMS.VCR.REC.1399.335

Health conditions studied**1****Description of health condition studied**

COVID19

ICD-10 code

NE82.OY

ICD-10 code description

This chapter includes certain conditions caused by a pathogenic organism or microorganism, such as a bacterium, virus, parasite, or fungus.

Primary outcomes**1****Description**

Improving the psychological states of patients with COVID 19

Timepoint

Before and after the intervention

Method of measurement

Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 8 sessions of cognitive and behavioral therapy. The content of the sessions includes the following: 1) Introduction to the cognitive-behavioral model 2) Ways to deal with depression and anxiety 3) relaxation training 4) Lifestyle techniques 5) Methods of logical analysis of thoughts 6) Teaching the problem solving skills 7) Cognitive errors and Methods of coping with them 8) Prevention of relapse. Each session lasts between 45 and 60 minutes and the duration of the course will be one month.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Psychiatry and Psychology Research Center

Full name of responsible person

Seyyed Salman Alavi

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Sponsors / Funding sources

1

Sponsor

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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
Tehran 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
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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

Not applicable

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

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

Data Dictionary

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