Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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
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Iran (Islamic Republic of)
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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
NE82.0Y

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

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Name of organization / entity
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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
Tehran University of Medical Sciences
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Person responsible for updating data

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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