Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of cognitive-behavioral intervention in reducing fear of COVID-19 symptoms, anxiety, depression, stress and improving the quality of life in people suffering from prolonged grief disorder due to the COVID-19

Protocol summary

Study aim

The effect of cognitive-behavioral intervention in reducing fear of COVID-19 symptoms, anxiety ,depression ,stress and improving the quality of life in people suffering from prolonged grief disorder due to the COVID-19

Design

This study is a randomized controlled trial with a parallel and double-blind design, conducted on 60 patients who have tested positive for COVID-19 and have been diagnosed with prolonged grief, in two hospitals in Tehran.

Settings and conduct

The samples of this study were collected from two hospitals in Tehran (Imam Khomeini Hospital and Ziaian Hospital). Face-to-face cognitive-behavioral intervention sessions will be held by a mental health specialist in a suitable environment while fully observing health protocols.

Participants/Inclusion and exclusion criteria

1. Being within the age range of 18 to 65 years old 2. Diagnosis of COVID-19 and the individual being in the recovery phase after treatment and experiencing long-term grief 3. Willingness to participate in the program and obtaining informed consent

Intervention groups

The participants in this research include an intervention group and a control group, with the intervention group receiving a 6-session cognitive-behavioral intervention.

Main outcome variables

The primary outcome in this study is the reduction of symptoms based on an interview, and the secondary outcomes are the reduction of fear of COVID-19, anxiety, depression, stress, and improvement in the quality of life in individuals with prolonged grief disorder caused by COVID-19.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230309057660N1**
Registration date: **2023-04-19, 1402/01/30**
Registration timing: **prospective**

Last update: **2023-04-19, 1402/01/30**
Update count: **0**

Registration date

2023-04-19, 1402/01/30

Registrant information

Name

Mojgan sadat Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4608 4429

Email address

mozhi.aba97@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of cognitive-behavioral intervention in reducing fear of COVID-19 symptoms, anxiety, depression, stress and improving the quality of life in people suffering from prolonged grief disorder due to the COVID-19

Public title
Psychological intervention and counseling to reduce symptoms of prolonged grief disorder

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Being within the age range of 18 to 65 years old Diagnosis of COVID-19 in an individual and the person is in the post-treatment recovery phase and also suffers from prolonged grief disorder Willingness to participate in the project and obtaining informed consent

Exclusion criteria:
Severe physical problems or visible organ impairment Patients with major depressive disorder, psychosis, or major psychiatric disorders were not included in the study and only initial drug treatments were performed for them

Age
From **18 years** old to **64 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals who have admission criteria receive a specific code, and then a certain number of them are randomly selected using a table of random numbers. Then, a random selection is made to determine the two experimental and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The intervention conditions in this study are such that blinding the participants to the type of intervention is not feasible. The outcome assessor will be responsible for questioning and will not be one of the intervention experts in the study, and the data analyst will not have information about the nature of the study groups' coding.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of the Tehran University of Medical Sciences

Street address
Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2023-04-10, 1402/01/21

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.033

Health conditions studied

1

Description of health condition studied
prolonged grief disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The primary outcome variable in this study is prolonged grief resulting from COVID-19

Timepoint
Assessment will be conducted in two stages, including prior to the start of cognitive-behavioral intervention, and one month after the final session of the intervention

Method of measurement
Using the Structured Clinical Interview for DSM Disorders (SCID)

Secondary outcomes

1

Description
Fear of COVID-19 Scale Score in Individuals with COVID-19-Related Prolonged Grief Disorder

Timepoint
Assessment will be conducted in two stages, including prior to the start of cognitive-behavioral intervention, and one month after the final session of the intervention

Method of measurement
Fear of COVID-19 Scale

2

Description
Depression scores in individuals with prolonged grief disorder due to COVID-19
Timepoint
Assessment will be conducted in two stages, including prior to the start of cognitive-behavioral intervention, and one month after the final session of the intervention
Method of measurement
Using the Depression-Anxiety-Stress Scale (DASS-21) questionnaire

3

Description
Quality of life score in individuals with prolonged grief disorder due to COVID-19
Timepoint
Assessment will be conducted in two stages, including prior to the start of cognitive-behavioral intervention, and one month after the final session of the intervention
Method of measurement
Using the WHOQOL-BREF questionnaire

4

Description
Anxiety scores in individuals with prolonged grief disorder due to COVID-19
Timepoint
Assessment will be conducted in two stages, including prior to the start of cognitive-behavioral intervention, and one month after the final session of the intervention
Method of measurement
Using the Depression-Anxiety-Stress Scale (DASS-21) questionnaire

5

Description
Stress scores in individuals with prolonged grief disorder due to COVID-19
Timepoint
Assessment will be conducted in two stages, including prior to the start of cognitive-behavioral intervention, and one month after the final session of the intervention
Method of measurement
Using the Depression-Anxiety-Stress Scale (DASS-21) questionnaire

Intervention groups

1

Description
Intervention group: Intervention group: The cognitive-behavioral intervention in this study is described as follows: In the first session, the participants are greeted and the cognitive-behavioral model (A-B-C) is introduced and its relationship with the treatment of prolonged grief disorder is explained. In the second session, coping strategies for depression and anxiety and improving the quality of life in patients with prolonged grief disorder are discussed. The third session focuses on teaching logical thinking techniques. The fourth session teaches problem-solving skills. The fifth session addresses cognitive errors and coping strategies for them. The final session focuses on relapse prevention
Category
Other

2

Description
Control group: The control group received usual care during this period
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Seyed salman Alavi
Street address
Blv.keshavarz
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6693 9004
Email
Imamhospital@tums.ac.ir

2

Recruitment center
Name of recruitment center
Ziaeian Hospital
Full name of responsible person
Seyed salman Alavi
Street address
Ziaian Educational-Medical Center" located at "Abouzar 20-meter street, at the junction of Ghazvin Street and Qapan Square, Abouzar, Tehran
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ziaeian@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyed Salman Alavi
Street address
Tehran University of Medical Sciences Headquarters, Boulevard Keshavarz
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vcr@tums.ac.ir
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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Seyed salman Alavi
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Person responsible for updating data

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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

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