

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 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

Ziaieian 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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Tehran

Province

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1366736511

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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,
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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

Full name of responsible person

Seyed salman Alavi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Name of organization / entity

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Seyed salman Alavi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

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Latest degree

Ph.D.

Other areas of specialty/work

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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