

# 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

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1366736511

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+98 21 5517 6810

#### **Fax**

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#### **Email**

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

**City**

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**Province**

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1333795914

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**Email**

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**

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

**Street address**

Ruzbeh Hospital, South Kargar St

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyed salman Alavi

**Position**

Researcher

**Latest degree**

Ph.D.

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+98 21 5541 3197

**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