

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jul 2026

### The Effect of Group Dialectical Behavior Therapy (DBT) on Covid-19 Caused Anxiety and its Complications on Mental Health in Adults Living in Pishva City.

#### Protocol summary

##### Study aim

Determining the effect of group Dialectical Behavior Therapy (DBT) on covid-19 caused anxiety and its complications on mental health in adults living in Pishva city.

##### Design

A clinical trial with intervention and control group, randomization by lottery, a sample size of 60.

##### Settings and conduct

The place and the method of study: The statistical population of this paper includes individuals aged 19 to 45 living in the city of Peshwa who are infected with Covid-19 in 2021-2022. This paper is a randomized controlled trial using a pre-test-post-test design with a control group receiving usual care. It is standard research. The intervention will be done at the Gholamreza Arab Salmani center located in Pishva city.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Covid-19 infected based on CPR test; adults in the age range of 19 to 45 years; adults living in Pishva city. Exclusion criteria: Dissociative psychotic disorders, drug and alcohol abuse; having underlying diseases such as cancer; mental retardation disorders; the presence of psychotic disorders.

##### Intervention groups

Intervention group: they will undergo eight 2-hour sessions of intervention once a week. Control group: there will be no intervention.

##### Main outcome variables

Corona anxiety; depression; aggression; sleep quality; mental health

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220902055850N1**

Registration date: **2022-09-13, 1401/06/22**

Registration timing: **prospective**

Last update: **2022-09-13, 1401/06/22**

Update count: **0**

##### Registration date

2022-09-13, 1401/06/22

##### Registrant information

###### Name

Zahra Kouhivardehkordi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 3672 4801

###### Email address

hasti.ham@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-23, 1401/07/01

##### Expected recruitment end date

2022-11-21, 1401/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Group Dialectical Behavior Therapy (DBT) on Covid-19 Caused Anxiety and its Complications on Mental Health in Adults Living in Pishva City.

**Public title**

The Effect of Group Dialectical Behavior Therapy (DBT) on Covid-19 Caused Anxiety

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Covid-19 infected based on CPR test Adults in the age range of 19 to 45 years Adults living in Pishva city

**Exclusion criteria:**

Dissociative psychotic disorders, Drug and alcohol abuse Having underlying diseases such as cancer Mental retardation disorders The presence of psychotic disorders

**Age**

From **19 years** old to **45 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**

In this study, a number of 60 subjects are selected according to similar research by convenience sampling method. Then, a random replacement is done by the random draw method so that each subject is assigned a number and we write down the numbers on the paper, then fold them and put them in a container. Later on, we mix the papers and take out the papers one by one and place one number in the first group and one number in the second group, respectively. Then random assignment will be done. In this way, one group will be assigned as the control group and the other group will be assigned as the intervention group by putting each group in an envelope and randomly taking out one envelope from the container and assigning it to the intervention group and the other envelope to the control group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Semnan Islamic Azad University

**Street address**

Islamic Azad University of semnan, shahrak daneshgahi

**City**

Semnan

**Province**

Semnan

**Postal code**

3513137111

**Approval date**

2022-08-23, 1401/06/01

**Ethics committee reference number**

IR.IAU.SEMNAN.REC.1401.034

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

Anxiety disorder, unspecified

**ICD-10 code**

F41.9

**ICD-10 code description**

Anxiety disorder, unspecified

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

Covid-19 caused anxiety: the score obtained from the coronavirus anxiety scale questionnaire prepared by Alipour, Abdullahzadeh, and Gadami (2019).

**Timepoint**

The measurement periods will be at the beginning of the study, one week before the beginning of the intervention, and one week after the end of the intervention (i.e. after 8 sessions of group Dialectical Behavior Therapy (DBT) intervention).

**Method of measurement**

Corona anxiety scale questionnaire

**2****Description**

Mental Health: The score obtained from the General Health Questionnaire (GHQ-28) was first adjusted by Goldberg (1972, citing Taqvi 2018).

**Timepoint**

The measurement periods will be at the beginning of the study, one week before the beginning of the intervention, and one week after the end of the intervention (i.e. after 8 sessions of group Dialectical Behavior Therapy (DBT) intervention).

**Method of measurement**

Goldberg mental health questionnaire

**3****Description**

Depression: the score obtained from the Depression, Anxiety, Stress Scale (DASS) questionnaire prepared by

Alvibond, (5991)

#### **Timepoint**

The measurement periods will be at the beginning of the study, one week before the beginning of the intervention, and one week after the end of the intervention (i.e. after 8 sessions of group Dialectical Behavior Therapy (DBT) intervention).

#### **Method of measurement**

Depression, Anxiety, Stress Scale Questionnaire (DASS)

### **4**

#### **Description**

Aggression: the score obtained from the Aggression Questionnaire (Buss & Perry, 1992)

#### **Timepoint**

The measurement periods will be at the beginning of the study, one week before the beginning of the intervention, and one week after the end of the intervention (i.e. after 8 sessions of group Dialectical Behavior Therapy (DBT) intervention).

#### **Method of measurement**

Bass and Perry Aggression Questionnaire

### **5**

#### **Description**

Sleep quality: the score obtained from the Pittsburgh Sleep Quality Index (PSQI). This questionnaire was developed in 1989 by Dr. Boyce and his colleagues at the Pittsburgh Psychiatric Institute.

#### **Timepoint**

The measurement periods will be at the beginning of the study, one week before the beginning of the intervention, and one week after the end of the intervention (i.e. after 8 sessions of group Dialectical Behavior Therapy (DBT) intervention).

#### **Method of measurement**

Pittsburgh Sleep Quality Questionnaire (PSQI)

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: the intervention group will undergo eight 2-hour sessions of group Dialectical behavior therapy (DBT) once a week. The treatment package used in this research will be derived from the group Dialectical behavior therapy (DBT) method derived from Linehan. The first session: First, the time of the sessions will be set, then the necessary explanations will be given to the subject regarding the rules and regulations of each session, followed by descriptions of the principles and methods of thinking and behavior in dialectical ways, and familiarity with mindfulness, rational mind, emotion mind, and wise mind. And then the subjects will be provided with explanations about the main goal of DBT, which is to learn how to live in the moment and develop

healthy ways to cope with stress, control their emotions and improve their relationships. At the end of the session, assignments will be given to the subjects. The second session: First, the assignments of the previous session will be reviewed, and then the distress tolerance skill will be explained to subjects to equip them with the ability to cope with themselves and the current situation. Also, basic skills of coping with disturbance, including different methods of diverting attention from self-harming behaviors, diverting attention through pleasurable activities, diverting attention to work or another subject, leaving the situation, etc., will be taught. Then we will draw up a plan for returning the attention, and self-relaxation, drawing up a relaxation plan, and at the end of the session, assignments will be given to the subjects. The third session: At the beginning of the session, the exercises of the previous session will be reviewed, and then in this session, advanced skills of distress tolerance, will be trained including imaging from a safe place, discovering values, living in the present, radical acceptance, developing new coping strategies, and developing a coping plan for the necessary situation. At the end of the session, assignments will be given to the subjects for the next session. The fourth session: At the beginning of the session, the exercises given in the previous session will be reviewed, and then the importance of mindfulness will be explained to the subjects. Mindfulness can help people to focus on the present and live in the moment, and this helps them to pay attention to what is going on inside them, and they will be taught basic skills of mindfulness, such as practicing inattention. The fifth session: At the beginning of the session, the assignments of the previous session will be reviewed, and in this session, advanced mindfulness skills including radical acceptance, beginner's mind, judgments and labels, non-judgment of conscious communication with others, daily schedule for mindfulness, awareness of obstacles to the implementation of exercises will be taught. At the end of the session, assignments will be given to the subjects for the next session. The sixth session: At the beginning of the session, the assignments of the previous session will be reviewed, then emotional regulation will be explained to the subjects. people can cope more effectively with strong emotions by regulating their emotions. The acquired skills help people identify, name, and change their feelings. We will teach basic and advanced skills such as emotions and how they work, emotional regulation skills, overcoming obstacles to healthy emotions, reducing physical vulnerability to emotions, increasing positive emotions, dealing with emotions, and solving problems. At the end of the session, assignments will be given to the subjects for the next session. The seventh session: At the beginning of the session, the assignments of the previous session will be reviewed, then effective communication will be explained to subjects it is said that interpersonal effectiveness helps them to be more assertive in relationships by maintaining a positive and healthy relationship (for example, being able to express themselves and say no). They will learn to listen and communicate better. In this regard, the basic skills of effective communication such

as passive-aggressive behavior, compatibility of my desires and theirs, the ratio of wants and needs, skills training, key interpersonal skills, and barriers to using interpersonal skills will be taught and at the end of the session, assignments will be given to the subjects for the next session. The eighth session: At the beginning of this session, the assignments of the previous session will be reviewed, and then advanced skills of effective communication such as identifying goals, adjusting the intensity of goals, boldness scripts, courageous listening, saying no, how to negotiate, how to analyze interpersonal problems will be taught. And at the end of the session, assignments will be given to the subjects for the next session.

#### Category

Treatment - Other

## 2

#### Description

Control group: no intervention is done for the control group. One week before the intervention, a pre-test was taken from the control group and they are placed on the waiting list. At the end of the intervention, they will be given a post-test and the results will be analyzed.

#### Category

Treatment - Other

## Recruitment centers

## 1

#### Recruitment center

##### Name of recruitment center

Gholamreza Arab Salmani Consulting Office

##### Full name of responsible person

Gholamreza Arab Salmani

##### Street address

Pishva, Shariati St., in front of the governorate of Toranj building, first floor, No. 69 Postal code: 3381833586

##### City

Pishva

##### Province

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##### Phone

+98 21 3672 7194

##### Email

reza9431@gmail.com

## Sponsors / Funding sources

## 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Mohammad Karim sohrabi

##### Street address

Islamic Azad University of Semnan Shahrak  
Daneshgahi

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amir\_sohraby@aut.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Islamic Azad University

#### 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

Islamic Azad University

##### Full name of responsible person

Zahra Kouhivar Dehkordi

##### Position

Dtudy University

##### Latest degree

Bachelor

##### Other areas of specialty/work

Psychology

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No.6, seylsepour al., 22Bahman ST., Shohada SQ.,  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Study University

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Zahra Kouhivar Dehkordi

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available