

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effectiveness of cognitive-behavioral therapy (CBT) on positive and negative psychotic symptoms and emotional regulation in patients with schizophrenia: A single-case pilot design for five patients with schizophrenia spectrum disorders

#### Protocol summary

##### Study aim

Determining the effectiveness of cognitive-behavioral therapy on positive and negative psychotic symptoms and emotional regulation in patients with schizophrenia spectrum disorders

##### Design

Clinical trial on five patients with schizophrenia spectrum disorders, With a single group, without blindness,

##### Settings and conduct

The field of research is to examine the cognitive-behavioral therapy on positive and negative psychotic symptoms and emotional regulation of patients with schizophrenia spectrum disorders. A clinical trial was performed at Razi Psychiatric Hospital in Tehran. Patient assessment was performed in all sessions. The study was before after type. First, baseline data were collected, then intervention phase data, and finally follow-up phase data were collected.

##### Participants/Inclusion and exclusion criteria

1: Diagnosis of schizophrenia based on DSM5 criteria; 2: Relative control of acute symptoms of patients; 3: Average age 18 to 45 years; 4: Voluntary attendance with informed written consent Research; 5: Research Having a minimum education with a diploma certificate; 6: Receiving a higher score on PANSS and DERS scales Compared to other patients; 7: Patients who have been in the ward for at least one week

##### Intervention groups

Five patients with schizophrenia spectrum disorders participated in treatment sessions on a single-subject basis. Each patient is considered as his/her own control. The patient's symptoms or adaptive functioning were assessed over time and during the sessions. In the intervention sessions, Patients learned how to cope with hallucinations and delusions, as well as how to express emotions.

##### Main outcome variables

Emotional regulation; positive and negative psychotic symptoms

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210412050937N2**

Registration date: **2021-12-14, 1400/09/23**

Registration timing: **retrospective**

Last update: **2021-12-14, 1400/09/23**

Update count: **0**

##### Registration date

2021-12-14, 1400/09/23

##### Registrant information

##### Name

Hamid Khakbaz

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5591 5322

##### Email address

ham.khakbaz@uswr.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-18, 1399/10/29

##### Expected recruitment end date

2021-03-18, 1399/12/28

**Actual recruitment start date**

2021-01-19, 1399/10/30

**Actual recruitment end date**

2021-03-18, 1399/12/28

**Trial completion date**

2021-03-18, 1399/12/28

**Scientific title**

The effectiveness of cognitive-behavioral therapy (CBT) on positive and negative psychotic symptoms and emotional regulation in patients with schizophrenia: A single-case pilot design for five patients with schizophrenia spectrum disorders

**Public title**

The effectiveness of cognitive-behavioral therapy (CBT) on positive and negative psychotic symptoms and emotional regulation in patients with schizophrenia spectrum disorders

**Purpose**

Education/Guidance

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

Diagnosis of schizophrenia spectrum disorders based on DSM5 criteria  
Relative control of acute symptoms of patients  
Average age 18 to 45 years  
Voluntary attendance with informed written consent  
Research  
Having a minimum education with a diploma certificate  
Receiving a higher score on PANSS and DERS scales  
Compared to other patients  
Patients who have been in the ward for at least one week

**Exclusion criteria:**

No criminal or judicial problems  
Alcohol or substance abuse  
Neurological disorders such as epilepsy, stroke or severe concussion  
High levels of disordered behavior or high risk of suicide or homicide  
Diagnosis Mental retardation. Severe learning disability

**Age**

From **18 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **5**

Actual sample size reached: **5**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

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

empty

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

Ethics Committee of University of Social Welfare and Rehabilitation Sciences

**Street address**

3rd floor, No. 362, Sheikh Akbari St., Shahr-e Rey, Tehran

**City**

Shahr-e-Rey

**Province**

Tehran

**Postal code**

1841744558

**Approval date**

2020-02-25, 1398/12/06

**Ethics committee reference number**

IR.USWR.REC.1399.013

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

Schizophrenia spectrum disorders

**ICD-10 code**

F20

**ICD-10 code description**

Schizophrenia

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

Positive and negative psychotic symptom score in Schizophrenia positive and negative symptom scale

**Timepoint**

Measures of The Positive and Negative Psychotic Symptoms two weeks before the start of the intervention (three baseline), all intervention sessions (16 Sessions), and 3 months after the end of the intervention (three follow-up lines)

**Method of measurement**

The Positive and Negative Psychotic Symptoms Scale

**2****Description**

Emotional regulation score in the Gratz and Roemer Emotional Regulation Difficulties Scale

**Timepoint**

Measures of emotional regulation two weeks before the start of the intervention (three baseline), all intervention sessions (16 sessions), and 3 months after the end of the

intervention (three follow-up lines)

#### Method of measurement

Gratz and Roemer Emotional Regulation Difficulties Scale

#### Secondary outcomes

empty

#### Intervention groups

##### 1

#### Description

Intervention group: Five patients with schizophrenia spectrum disorders participated in treatment sessions on a single-subject basis. The Cognitive-behavioral Therapy Manual consists of 16 sessions, each lasting 60 minutes. Two treatment sessions are performed for each patient every week. The duration of all treatment sessions was 60 days. CBT offers assessment of psychotic symptoms, Psycho-Education, working on hallucinations and delusions, self-management programs, stress vulnerability model, relaxation technique and treatment tasks.

#### Category

Treatment - Other

#### Recruitment centers

##### 1

#### Recruitment center

##### Name of recruitment center

Razi Educational And Therapeutic Psychiatric Center

##### Full name of responsible person

Hamid Khakbaz

##### Street address

Amin Abad, Shahid Rastegar Boulevard, Taghiabad Intersection, Shahr-e-Rey

##### City

Shahr-e-Rey

##### Province

Tehran

##### Postal code

18664

##### Phone

+98 21 3340 1220

##### Email

Khakbaz.hamid@gmail.com

#### Sponsors / Funding sources

##### 1

#### Sponsor

##### Name of organization / entity

University of social welfare and rehabilitation sciences

##### Full name of responsible person

Hamidreza Khorram Khorshid

##### Street address

Koodakyar Deadened, Deneshjoo BLV, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985713834

##### Phone

+98 21 7173 2000

##### Email

khakbaz.hamid@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

##### Full name of responsible person

Hamid Khakbaz

##### Position

Psychologist

##### Latest degree

Master

##### Other areas of specialty/work

Psychology

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#### Person responsible for scientific inquiries

#### Contact

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University of social welfare and rehabilitation sciences

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Sharing plan**

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

After deleting the confidential information, I will share the data file of the patients of this research with other researchers; including age, sex, occupation, education and marital status.

**When the data will become available and for how long**

Start of access period 3 months after the end of treatment and follow-up

**To whom data/document is available**

The data is only available to research colleagues and other researchers and practitioners

**Under which criteria data/document could be used**

The data can be used for publication in scientific research journals. Researchers are not allowed to do any analysis and they can only view and receive the data and analyze it. Researchers are also required to make a written commitment not to publish the data file.

**From where data/document is obtainable**

Send me an email: khakbaz.hamid@gmail.com Also refer to the following address: Hamid Khakbaz, Department of Counseling, University of Social Welfare and Rehabilitation Sciences, Daneshjoo Blvd., Evin, Tehran phone number: 09129484583

**What processes are involved for a request to access data/document**

After sending me an email and confirming the identity of the applicant, and the final confirmation of the research colleagues, the data will be sent to them. The approximate time will be 2 to 3 months

**Comments**