

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 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

AgeFrom **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

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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

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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

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

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Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

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Person responsible for updating data

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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