

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the effectiveness of Acceptance and Commitment-Based Therapy (ACT) on Positive and Negative Psychotic Symptoms and Emotion regulation of Patients with schizophrenia spectrum disorders: A Single-Subject study

Protocol summary

Study aim

Determining the effectiveness of Acceptance and Commitment Therapy on positive and negative symptoms and emotional regulation of 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 effectiveness of acceptance and commitment based therapy on positive and negative symptoms and emotional regulation of patients with schizophrenia. 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

Inclusion criteria; Patients with the diagnosis of a psychiatrist based on DSM5 criteria have positive and negative psychotic symptoms and their acute symptoms are in relative control; being at the age of 18- 45 years; Patient's score in the positive and negative symptoms questionnaire and in the emotional regulation questionnaire should be higher than other patients. Non inclusion criteria; Patients with criminal and judicial problems; Patients who according to a psychiatrist have personality disorders;

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: **IRCT20210412050937N1**

Registration date: **2021-07-22, 1400/04/31**

Registration timing: **retrospective**

Last update: **2021-07-22, 1400/04/31**

Update count: **0**

Registration date

2021-07-22, 1400/04/31

Registrant information

Name

Hamid Khakbaz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5591 5322

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

2021-01-14, 1399/10/25

Actual recruitment end date

2021-03-08, 1399/12/18

Trial completion date

2021-03-08, 1399/12/18

Scientific title

Evaluation of the effectiveness of Acceptance and Commitment-Based Therapy (ACT) on Positive and Negative Psychotic Symptoms and Emotion regulation of Patients with schizophrenia spectrum disorders: A Single-Subject study

Public title

Effectiveness of Acceptance and Commitment-Based Therapy (ACT) on Positive and Negative Psychotic Symptoms and Emotion regulation in Patients with schizophrenia spectrum disorders

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with the diagnosis of a psychiatrist based on DSM5 criteria, have positive and negative psychotic symptoms and their acute symptoms are in relative control Being at the age of 18 and 45 years Patients enter the study voluntarily and with informed consent or the opinion of the guardian Patient's score in the positive and negative symptoms questionnaire and in the emotional regulation questionnaire should be higher than other patients

Exclusion criteria:

Patients who have criminal and judicial problems in terms of the judiciary (due to possible problems in accessing to patients) Patients who have mental disorders other than schizophrenia according to a psychiatrist Patients who have a drug addiction problem for any reason or have been admitted to a psychiatric hospital due to substance abuse Patients with neurological disorders such as epilepsy, stroke, or severe concussion (based on patient records)

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. 12, Shahsavari Alley, Asadollahi St., Shahr-e Rey, Tehran

City

Tehran

Province

Tehran

Postal code

1847888159

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 symptom score in Schizophrenia positive and negative symptom questionnaire

Timepoint

Measures of The Positive and Negative 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 Symptoms Questionnaire

2**Description**

Emotional regulation score in the Gratz and Roemer

Emotional Regulation Difficulties Questionnaire

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 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Five patients with schizophrenia spectrum disorders participated in treatment sessions on a single-subject basis. The Acceptance and Commitment Therapy Manual consists of 16 sessions, each lasting 50 minutes. Two treatment sessions are performed for each patient every week. The duration of all treatment sessions is 60 days. In an ACT model, patients are taught to accept their feelings, as feelings; notice their own thoughts; contact the present moment; focus on their values; and act in accordance with their values. In each session, a complete assessment of positive and negative psychotic symptoms and problems related to the patient's emotional regulation is performed. During this session, the therapist also notes the participant's degree of struggle with symptoms and motivation for change as basic indicators of the most useful starting point for subsequent interventions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi educational and therapeutic psychiatric center

Full name of responsible person

Mohammad Hadi Safi

Street address

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

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khakbaz.ham@uswr.ac.ir

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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1985713834

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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 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 ham.khakbaz@uswr.ac.ir And the following 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