Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of Acceptance and Commitment Therapy (ACT) on Stigma Levels in Individuals with Schizophrenia Disorders

Protocol summary

Study aim

Overall Objective: To determine the effect of an acceptance and commitment-based intervention on the level of stigma in people with schizophrenia. There are also minor goals.

Design

It is a simple randomization that places people in two groups of 30: control and intervention.

Settings and conduct

Eligible patients will be recruited from the Schizophrenia Patients Support Association (AHBA) and Roozbeh Psychiatric Center after confirming the inclusion and exclusion criteria. Written informed consent will be obtained before enrollment, and the study procedures will be explained to all participants. This study will be conducted using a single-blind design.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:• Minimum literacy level sufficient to complete the questionnaires.• Stable clinical condition or partial recovery.•Ability to understand instructions and participate in group sessions.•Written informed consent provided by the legal guardian.•Age ≥18 years. Exclusion Criteria: • Development of an acute psychotic disorder during the sessions.• Drug or alcohol use that affects the ability to participate in the sessions.• Participants who have missed more than two sessions.

Intervention groups

Participants in the intervention group will receive ACT , in addition to usual care, in the form of eight 90-minute semi-structured group sessions.Participants in the control group will receive usual care and routine treatment only during the study period and will not receive any ACT. Outcome assessments will be performed at the same time points as in the intervention group.

Main outcome variables

1. Acceptance and Commitment Therapy (ACT) intervention: Patient assigned to the intervention or control group for 8 90-minute sessions 2. Stigma score: Total score of the stigma questionnaire based on a four-point Likert scale from 1 (completely disagree) to 4 (completely agree)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260607069693N1**
Registration date: **2026-07-15, 1405/04/24**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-15, 1405/04/24**
Update count: **0**

Registration date

2026-07-15, 1405/04/24

Registrant information

Name

Dorsa Khayatali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2245 6663

Email address

dorsa.khayatali@iau.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-07-23, 1405/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the Effect of Acceptance and Commitment Therapy (ACT) on Stigma Levels in Individuals with Schizophrenia Disorders

Public title
Investigating the Effect of Acceptance and Commitment Therapy (ACT) on Stigma Levels in Individuals with Schizophrenia Disorders

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 years and older Minimum literacy level sufficient to complete the questionnaires Stable clinical condition or partial recovery. Ability to understand instructions and cooperate in group sessions. Informed and written consent to participate in the study from the guardian of individuals with schizophrenia disorders

Exclusion criteria:
Development of an acute psychotic disorder during the sessions. Drug or alcohol use that affects the ability to participate in the sessions. Development of severe physical complications or chronic illness that prevents regular attendance at sessions, unwillingness or withdrawal from continuing cooperation during the study. Participation in other concurrent psychotherapy interventions that may affect the results of the ACT. Severe cognitive problems that make it impossible to complete the questionnaire. Participants who have missed more than two sessions.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting up to 60 eligible participants through purposive sampling and obtaining written informed consent, participants will be randomly allocated to the intervention and control groups using simple randomization with a 1:1 allocation ratio. The unit of randomization is the individual participant. The random allocation sequence will be generated using SPSS statistical software. Based on the generated random sequence, each participant will be assigned to either the intervention or the control group after completion of the baseline assessment. To ensure allocation concealment, the randomization sequence will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE). After enrollment and baseline assessment, the corresponding envelope will be opened in sequence to reveal the participant's group assignment.

Blinding (investigator's opinion)
Single blinded

Blinding description
In a single-blind study, information that could skew the results of the experiment is hidden from the participant, but the person conducting the experiment is aware of it.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran Islamic Azad University of Medical Sciences

Street address
Islamic Azad University, Tehran Medical Sciences Branch Khalili Dead End, South Roudaki St., Khaghani St., Shariati St. Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1916893813

Approval date
2026-06-09, 1405/03/19

Ethics committee reference number
IR.IAU.TMU.REC.1405.074

Health conditions studied

1

Description of health condition studied
Schizophrenia spectrum disorders

ICD-10 code
F20-F29

ICD-10 code description
Schizophrenia, schizotypal and delusional disorders(F20-F29)

Primary outcomes

1

Description
1. Acceptance and Commitment Therapy (ACT) intervention, assigning the patient to the intervention or control group for 8 sessions of 90 minutes. 2. Stigma level: total score of the stigma questionnaire based on a

four-point Likert scale from 1 (completely disagree) to 4 (completely agree).

Timepoint

At the beginning of the study, a questionnaire is filled out. After completion of the work, the subject is immediately re-measured and the questionnaire is filled out again after a month.

Method of measurement

the Internalized Stigma of Patients with Mental Disorders (ISMI) questionnaire.To measure the level of stigma in patients with schizophrenia, the Internalized Stigma of Patients with Mental Disorders (ISMI) questionnaire is used.This questionnaire was designed by Ritsher et al. in 2003 and is considered one of the most valid tools for assessing stigma in psychiatric patients. The ISMI questionnaire consists of 29 items and assesses five main components: alienation, acceptance of stereotypes, experience of discrimination, social withdrawal, and resistance to stigma.

Secondary outcomes

1

Description

Internalized stigma score. Outcome measure: Internalized Stigma of Mental Illness (ISMI) questionnaire. Timepoint: At baseline, immediately after the intervention, and one month after the intervention

Timepoint

At the beginning of the work

Method of measurement

Using a demographic information questionnaire

Intervention groups

1

Description

Intervention group: Participants in this group will receive Acceptance and Commitment Therapy (ACT) in addition to routine psychiatric care. The intervention will be delivered as eight 90-minute semi-structured group sessions, conducted twice weekly over four weeks. The sessions will be conducted by the principal investigator, who has completed formal training in Acceptance and Commitment Therapy (ACT), according to the university-approved treatment protocol. The intervention includes psychoeducation about the ACT model, acceptance of thoughts and emotions, mindfulness, cognitive defusion, self-as-context, values clarification, committed action, skills practice, and relapse prevention.

Category

Other

2

Description

Control group: Participants in this group will receive routine psychiatric care only, including pharmacotherapy, regular psychiatric follow-up, and other standard clinical services provided by the treatment center. They will not receive Acceptance and Commitment Therapy (ACT) during the study period. Outcome assessments will be performed at the same time points as those in the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Schizophrenia Patients Support Association (AHBA)

Full name of responsible person

Taybeh Dehbashizadeh

Street address

No. 116, Eskandari St., Moradi St., Qazvin St., Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1955867571

Phone

+98 21 5541 0001

Email

spsahebba@gmail.com

Web page address

https://spsahebba.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Seyed Ali Abtahi

Street address

Floors 7 and 9, Block 6, Central Organization of Islamic Azad University, Shohada-ye Hesarak Boulevard, Shahid Mohammad Mehdi Tehranchi Square, End of Shahid Sattari Expressway (North), Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1477893780

Phone

+98 21 4791 6949

Email

med@iau.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
Dorsa Khayatali
Position
Master's student in psychiatric nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 6, Razaghi Alley, Qaem Residential Complex, Mini City, Tehran, Iran – 3rd Floor.
City
Tehran
Province
Tehran
Postal code
1955867571
Phone
+98 21 2245 6663
Email
Dorsa.khayatali@iau.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Jamileh Mohatsami
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
No. 67, Boojarian St., Madaen Area, Narmak, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1649746841
Phone
+98 21 7744 0770
Email
beh@iau.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dorsa Khayatali
Position
Master's student in psychiatric nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 6, Razaghi Alley, Qaem Residential Complex, Mini City, Tehran, Iran – 3rd Floor.
City
Tehran
Province
Tehran
Postal code
1955867571
Phone
+98 21 2245 6663
Email
Dorsa.khayatali@iau.ir

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