Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparison of the effectiveness of Acceptance and Commitment Therapy and Cognitive-Behavioral Therapy on emotional adaptation, mental well-being, and psychological flexibility in parents of patients with schizophrenia

Protocol summary

Study aim
Compare the effectiveness of Acceptance and Commitment Therapy and Cognitive Behavioral Therapy on emotional adjustment, psychological well-being, and psychological flexibility in parents of patients with schizophrenia.

Design
A controlled, parallel-group, unblinded, randomized clinical trial on 60 patients

Settings and conduct
Mehr Counseling Center, Tehran. Nine-session weekly interventions by clinical psychologist. Control group receives no intervention. Assessments at baseline, post-intervention, and 45-day follow-up.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Parents who have a patient with schizophrenia disorder; Being diagnosed with emotional adjustment, mental well-being, and psychological flexibility problems based on questionnaire scores; Ability to read and write; Exclusion criteria: Substance abuse; Receiving simultaneous psychological treatments; Having acute and chronic physical illnesses, including epilepsy, skeletal problems, and respiratory diseases

Intervention groups
First intervention group: 9 sessions of acceptance and commitment therapy will be provided. The interval between sessions is one week. Each session lasts 90 minutes. The treatment is individual. Second intervention group: 9 sessions of cognitive-behavioral therapy will be provided. The interval between sessions is one week. Each session lasts 90 minutes. The treatment is individual. Control group: This group will not receive the treatment.

Main outcome variables
Emotional Adjustment Scale, Psychological Well-Being, Cognitive flexibility score

General information

Reason for update

Acronym
ACT-CBT Schizo Parents

IRCT registration information
IRCT registration number: **IRCT20250817066892N1**
Registration date: **2025-10-26, 1404/08/04**
Registration timing: **prospective**

Last update: **2025-10-26, 1404/08/04**
Update count: **0**

Registration date
2025-10-26, 1404/08/04

Registrant information

Name
Bahareh Abdollahzadeh

Name of organization / entity
Islamic Azad University, Tonekabon Mazandaran Branch

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-06, 1404/08/15

Expected recruitment end date
2025-11-26, 1404/09/05

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison of the effectiveness of Acceptance and Commitment Therapy and Cognitive-Behavioral Therapy on emotional adaptation, mental well-being, and psychological flexibility in parents of patients with schizophrenia

Public title
A comparative study of two psychological treatment methods on the well-being and adjustment of parents of patients with schizophrenia.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Parents of patients with schizophrenia who have an active file at the Tehran Welfare Organization Diagnosing emotional problems, mental well-being, and psychological resilience based on questionnaire scores Ability to read and write
Exclusion criteria:
Being diagnosed with a mental illness by a psychiatrist Having acute and chronic physical illnesses such as epilepsy, skeletal disorders, and respiratory insufficiency Using psychiatric drugs at the time of study admission Unable to complete questionnaires Failure to attend the initial intervention sessions
Age
To **65 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
The process of random allocation of participants to three groups of interventions and control includes both creating a random sequence and concealing the random allocation. Firstly, using the random sequence rule, 60 papers for participants of the interventions and control groups (which will be marked with A, B, and C and will not be defined to avoid bias) will be thrown into a lottery container and then the papers will be removed from the lottery container - without replacement - and the created sequence will be recorded. Then, using the snooze method, 60 envelopes will be prepared and each of the random sequences created will be recorded on a card and will be placed in the envelopes in order, and the envelopes will be also numbered. Then, the envelopes will be given to the participants based on the order of entering the study, so the grouping of each will be determined.
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
Research Ethics Committee of Islamic Azad University, Tonekabon Branch
Street address
Vali Abad Ave, Khalij Fars Blv, Tonekabon
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Postal code
4684161167
Approval date
2025-07-22, 1404/04/31
Ethics committee reference number
IR.IAU.TON.REC.1404.122

Health conditions studied

1

Description of health condition studied
Schizophrenia
ICD-10 code
F20-F29
ICD-10 code description
اختلال اسکیزوفرنی

Primary outcomes

1

Description
Emotional adjustment score
Timepoint
Before intervention (pre-test), after intervention (post-test), 3 months after intervention (follow-up)
Method of measurement
Emotional Adjustment Scale by Rabio et al. (2007)

2

Description
Psychological Well-Being score
Timepoint

Before intervention (pre-test), after intervention (post-test), 3 months after intervention (follow-up)

Method of measurement

Psychological Well-Being Questionnaire by Goyers and Margamiov (2003).

3

Description

Cognitive flexibility score

Timepoint

Before intervention (pre-test), after intervention (post-test), 3 months after intervention (follow-up)

Method of measurement

Cognitive Flexibility Inventory by Denis and Vendral (2010)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The intervention that this group will receive is acceptance and commitment therapy. Nine individual 90-minute sessions based on Hayes' protocol, delivered once per week by a licensed clinical psychologist. The intervention focuses on six core processes: cognitive defusion, acceptance, contact with the present moment, self-as-context, values clarification, and committed action. Sessions are conducted in a private counseling room.

Category

Behavior

2

Description

Intervention group 2: The intervention that this group will receive is acceptance and commitment therapy. Nine individual 90-minute sessions, delivered once per week by a licensed clinical psychologist. The sessions include cognitive restructuring, identifying and challenging maladaptive thoughts, behavioral activation, stress management, and problem-solving training. The intervention is based on established CBT principles and guidelines, and sessions are conducted in a private counseling room.

Category

Behavior

3

Description

Control group: Participants in this group will not receive any active psychological intervention during the study period and will continue their usual care. After the completion of the trial, they will be provided with an educational package on psychological skills.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr counseling center

Full name of responsible person

Afsaneh Vakili

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Masoud Ghane

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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

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 of tonekabon
Full name of responsible person
Bahareh Abdollahzadeh
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)
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
De-identified dataset and related documentation for the randomized controlled trial on the effectiveness of Acceptance and Commitment Therapy and Cognitive Behavioral Therapy in parents of patients with schizophrenia.
When the data will become available and for how long
Available upon reasonable request starting 6 months after publication of the main study results and for a

period of 3 years.

To whom data/document is available

Qualified researchers affiliated with academic or non-profit research institutions who submit a formal request and agree to the data use terms.

Under which criteria data/document could be used

For non-commercial academic research purposes only, with the requirement to cite the original study and comply with ethical guidelines for data use.

From where data/document is obtainable

b.abdollahzadeh@iau.ir

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

Submit a formal written request via email, including the research purpose, institutional affiliation, and a signed agreement to the data use terms. The request will be reviewed by the principal investigator, and applicants will be notified of the decision via email.

Comments

All shared data will be fully anonymized to protect participant confidentiality. Data will be available upon reasonable request starting six months after publication of the main study results and for three years thereafter.