Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Impact of Group Cognitive Behavioral Therapy on the Mental Health, Stigma, and Social Capital of Patients with Severe Psychiatric Disorders (Bipolar Disorder, Schizophrenia, and Schizoaffective Disorder) and Its Effect on Their Caregivers

Protocol summary

Study aim

To determine the effect of cognitive-behavioral group therapy on the mental health, stigma, and social capital of patients with severe psychiatric disorders and on the stigma and social capital of caregivers of patients in comparison with a matched control group

Design

To investigate the effectiveness of a group cognitive behavioral therapy intervention on improving severe psychiatric symptoms. A controlled, parallel-group, triple-blind, randomized study on 60 patients and their caregivers. Simple randomization on available samples using statistical randomization software

Settings and conduct

30 severely mentally ill patients from the Community Mental Health Services Center (Siraj) and caregivers from the Siraj Center and 30 other patients and caregivers from psychiatric clinics To maintain concealment, researchers, outcome assessors, and data analysts will be blinded to group allocation, which will be administered by two participants who are not involved in the study.

Participants/Inclusion and exclusion criteria

- Diagnosis confirmed by two psychiatrists according to DSM-5-TR - Mental status "stable" (PANSS score below threshold). - Age between 18 and 65 years. - Informed consent.

Intervention groups

Patients with severe mental disorders at the Siraj Mental Health Community Center, East Karaj, and their caregivers

Main outcome variables

Determining the effect of group CBT intervention on depression, anxiety, suicidal thoughts, stigma, quality of life, and social capital of patients with severe psychiatric disorders in comparison with the control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251128068139N1**
Registration date: **2025-12-14, 1404/09/23**
Registration timing: **prospective**

Last update: **2025-12-14, 1404/09/23**
Update count: **0**

Registration date

2025-12-14, 1404/09/23

Registrant information

Name
Rahim Badrfam
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-08-22, 1405/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Impact of Group Cognitive Behavioral Therapy on the Mental Health, Stigma, and Social Capital of Patients with Severe Psychiatric Disorders (Bipolar Disorder, Schizophrenia, and Schizoaffective Disorder) and Its Effect on Their Caregivers

Public title
The Impact of Group Cognitive Behavioral Therapy on the Mental Health, Stigma, and Social Capital of Patients with Severe Psychiatric Disorders and Its Effect on Their Caregivers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis confirmed by two psychiatrists based on DSM-5-TR "Stable" mental status (operational definition: PANSS score below threshold Age between 18 and 65 years Informed consent

Exclusion criteria:
Absence of more than 2 sessions of the intervention Exacerbation of the severity of the disease symptoms requiring immediate hospitalization Intention to withdraw from the study at any stage

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization in this study will be straightforward and will rely on the available samples through simple randomization. Once eligible patients have been identified, statistical randomization software will be utilized to assign them to either the intervention or control groups. This randomization will be conducted on an individual basis. Patients will be divided into the two groups based on relevant psychiatric diagnoses and demographic criteria. To ensure impartiality, the researchers conducting the study (who will be implementing group training using cognitive behavioral therapy), the outcome assessor, and the researcher analyzing the data will be kept unaware of the assignment of patients to the intervention and control groups. The allocation will be managed by two participants who are not involved in the research design.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The researchers conducting this study, who will implement group training using cognitive behavioral therapy and the outcome assessors who will collect the data, as well as the researcher who will analyze it, will be unaware of how patients are allocated to either the intervention or control groups. Patient allocation will be managed by two participants who are not involved in the study's design. Therefore, the study will be conducted in a triple-blind manner. The authors drafting the manuscript will also remain unaware of the patient allocations, including their identities and referral sites. All patients and caregivers considered for participation in the study will be fully informed about the study before it begins, and written informed consent will be obtained from them prior to the start of the research.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Alborz University of Medical Sciences

Street address
Mohammadshahr to Mahdasht Road, Baghestan Boulevard

City
Karaj

Province
Alborz

Postal code
3139865787

Approval date
2025-11-08, 1404/08/17

Ethics committee reference number
IR.ABZUMS.REC.1404.257

Health conditions studied

1

Description of health condition studied
Severe Psychiatric Disorders

ICD-10 code
F20

ICD-10 code description
Schizophrenia

2

Description of health condition studied
Severe Psychiatric Disorders
ICD-10 code
F31
ICD-10 code description
Bipolar disorder

3

Description of health condition studied
Severe Psychiatric Disorders
ICD-10 code
F25
ICD-10 code description
Schizoaffective disorders

Primary outcomes

1

Description
Depression score on the Beck Depression Inventory
Timepoint
Score measurement of depression at the beginning of the study (before the intervention) and at weeks 6, 8, 10, and 18 after the start of group cognitive-behavioral therapy.
Method of measurement
Beck Depression Inventory

2

Description
Beck Anxiety Inventory score
Timepoint
Score measurement of anxiety at the beginning of the study (before the intervention) and at weeks 6, 8, 10, and 18 after the start of group cognitive-behavioral therapy
Method of measurement
Beck Anxiety Inventory

3

Description
Beck suicide score
Timepoint
Score measurement f suicide at the beginning of the study (before the intervention) and at weeks 6, 8, 10, and 18 after the start of group cognitive-behavioral therapy
Method of measurement
Beck Suicide Questionnaire

4

Description
Stigma Score at World Psychiatric Organization Stigma Questionnaire
Timepoint
Score measurement of stigma at the beginning of the study (before the intervention) and at weeks 6, 8, 10, and 18 after the start of group cognitive-behavioral therapy
Method of measurement
World Psychiatric Organization Stigma Questionnaire

5

Description
Social Capital Score at Nahapit and Ghoshal Questionnaire
Timepoint
Score measurement of Social Capital at the beginning of the study (before the intervention) and at weeks 6, 8, 10, and 18 after the start of group cognitive-behavioral therapy
Method of measurement
Social Capital Questionnaire Nahapit and Ghoshal Questionnaire

Secondary outcomes

1

Description
Quality of life score on the quality of life questionnaire
Timepoint
Score measurement of quality of life at the beginning of the study (before the intervention) and at weeks 6, 8, 10, and 18 after the start of group cognitive-behavioral therapy
Method of measurement
Quality of life questionnaire

Intervention groups

1

Description
First intervention group: Patients with severe psychiatric disorders (bipolar, schizophrenia, and schizoaffective)
Category
Treatment - Other

2

Description
Second intervention group: Caregivers of patients with severe psychiatric disorders (bipolar, schizophrenia, and schizoaffective)
Category
Treatment - Other

3

Description
First control group: Patients with severe psychiatric disorders (bipolar, schizophrenia, and schizoaffective)
Category
Placebo

4

Description
Second control group: caregivers of patients with severe psychiatric disorders (bipolar, schizophrenia, and schizoaffective)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Saraj Mental Health Social Center, East Karaj
Full name of responsible person
Dr.Rahim Badrfam
Street address
Takhti Street-45 meters of Kaj Boulevard- Azimieh
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2

Recruitment center
Name of recruitment center
Dr. Ali Shariati Hospital
Full name of responsible person
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Baghestan Boulevard, Mohammadshahr to Mahdasht Road
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3

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Dr. Mohsen Heidari Mokarrar
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Mansour Bakht St.,Imam Khomeini Blvd.,Mohammad Shahr
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Dr. Alireza Dehghan Nayeri
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Saffarian Alley, Chehelopanj meters Golshahr
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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
Alborz University of Medical 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
Alborz University of Medical Sciences
Full name of responsible person
Dr.Rahim Badrfam
Position
Specialist physician
Latest degree
Specialist
Other areas of specialty/work

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rbadrfam@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
In order to maintain maximum confidentiality of patient information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available