

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparing the Effectiveness of Social Cognition and Interaction Training (SCIT) Based Group Therapy on Social Cognition and Functioning in Schizophrenic and Bipolar Disorder Patients

Protocol summary

Study aim

Investigating the effectiveness of Social Cognition and Interaction Training (SCIT) group therapy on social cognition and function of patients with schizophrenia and bipolar disorder

Design

Controlled Clinical trial, Random number table will be used for randomization

Settings and conduct

Among the inpatients with schizophrenia or bipolar disorder in the Ostad Moharary Neuropsychiatric Hospital, after explaining the considerations, 30 patients will be selected from each disorder using convenience sampling method. Subjects will be divided into control and intervention groups using randomization. Both will get treatment as usual (TAU). The intervention group will have 18 sessions of SCIT. Both groups will be tested in pre-test, post-test and follow-up.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: inpatients with a diagnosis of schizophrenia and bipolar disorder, over 18 yo, Ability to understand experimental assignments, ability to see and hear normally Exclusion Criteria: Presence of current or past developmental disorders, severe head trauma, a history of substance abuse in the past 6 months

Intervention groups

Intervention group beside treatment as usual (TAU) will have 18 sessions of SCIT group therapy four times a week which is designed to help normalize social cognition by remediating deficits and decreasing biases; This group therapy consists of 3 phase (Introduction and Emotions, Figuring Out Situations & Integration). In this therapy Various aids such as paper, SCIT PowerPoint slideshows and video vignettes and varied tasks are used. Control group will only get TAU and participate in evaluation in 3 discrete time periods (pre-test, post-test & follow-up).

Main outcome variables

Social cognition score, social function score, clinical symptoms score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210811052149N1**

Registration date: **2023-03-09, 1401/12/18**

Registration timing: **retrospective**

Last update: **2023-03-09, 1401/12/18**

Update count: **0**

Registration date

2023-03-09, 1401/12/18

Registrant information

Name

Shima Dehghanzadeh

Name of organization / entity

Shiraz University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-11, 1400/06/20

Expected recruitment end date

2021-12-18, 1400/09/27

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the Effectiveness of Social Cognition and Interaction Training (SCIT) Based Group Therapy on Social Cognition and Functioning in Schizophrenic and Bipolar Disorder Patients

Public title
Effectiveness of Social Cognition and Interaction Training (SCIT) Based Group Therapy in Schizophrenic and Bipolar Disorder Patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 known-case of Schizophrenia Disorder known-case of Bipolar Disorder Be at least 18 years old Ability to understand experimental assignments Ability to see and hear normally
Exclusion criteria:
 Presence of current or past developmental disorders severe head trauma a history of substance abuse in the past 6 months

Age
From **18 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
For each intervention group (each bipolar group and Schizophrenia group) 30 subjects will be chosen from available candidates using convenience sampling method. Subjects will be split randomly between two groups, control and intervention groups, each group containing 15 persons. For randomizing the splitting process; initially, an integer code between 01 and 30 will be assigned to each person, then we move and stop our finger randomly and blindfolded on a RAND Corporation random number table, we move on that chosen row to find the corresponding random number and consider the last two digits of the random number. A successful random number is generated if the number is between 01 and 30. The process will continue till 15 random integers in the desired interval is made. 15 selected codes are in the intervention group and the rest are in the control group.

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
 Ethics committee of Shiraz University of Medical Sciences
Street address
 7th Floor, Administration Building of Shiraz University of Medical Sciences, Zand St., Shiraz, Iran
City
 Shiraz
Province
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Postal code
 71348-14336
Approval date
 2021-07-28, 1400/05/06
Ethics committee reference number
 IR.SUMS.REC.1400.389

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20

ICD-10 code description
Schizophrenia

2

Description of health condition studied
Bipolar disorder

ICD-10 code
F31

ICD-10 code description
Bipolar disorder

Primary outcomes

1

Description
social cognition

Timepoint
Before intervention, after intervention & 3 months after in follow-up

Method of measurement
The Hinting Task, and The Penn Emotion Recognition

2**Description**

social function

Timepoint

Before intervention, after intervention & 3 months after in follow-up

Method of measurement

short form of Social Functioning Scale (SFS), and Nurses' Observation Scale for Inpatient Evaluation (NOSIE)

3**Description**

clinical symptoms

Timepoint

Before & after intervention

Method of measurement

The Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: are consisted of 15 patients who will have group therapy for 18 sessions of 45 to 60 minutes long. Group-therapy sessions will be held 4 times a week. Participants will continue their treatment as usual (TAU). This group therapy consists of 3 phase (Introduction and Emotions, Figuring Out Situations & Integration). Each session has a main topic and target which will be trained by discussing more elaborate subtopics and by practicing various pieces of training. In this therapy Various aids such as paper, PowerPoint slideshows and SCIT video vignettes and varied tasks are used. In the first part, the basic emotions, the relationship between emotions and social situations, and the recognition of emotions according to facial expressions are discussed. The goal of the second part of treatment is to learn and use social cognitive methods to avoid the pitfalls of jumping to conclusions related to social situations. These strategies include generating multiple attributions for negative events, distinguishing social facts from social guesses, tolerating ambiguity in social situations, etc. In the third part, the integration of the skills learned up to this stage and the application of these skills in the lives of patients are discussed. At this stage, patients are encouraged to bring in problematic situations from their daily lives; the group then analyzes the situations and finds behavioral strategies to take steps to reduce interpersonal distress based on the skills they have learned during this treatment.

Category

Treatment - Other

2**Description**

Control group: consisted of 15 subjects that will not receive any extra treatment and continue their treatment as usual. They will join pre-test, post-test and follow-up before, after and 3 months later than the intervention respectively.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ostad Moharary Neuropsychiatric Hospital

Full name of responsible person

Dr Leila Razeghian Jahromi

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Full name of responsible person

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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
Shiraz 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
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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

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data (without participant personal information) as questionnaire's raw scores, basic consent form, and general protocols is available for fellow researchers via

email application, 6 months after publication of first paper.

When the data will become available and for how long

Accessible 6 months after publication of paper.

To whom data/document is available

For whom the data is useful and usable.

Under which criteria data/document could be used

using in the fields of psychology, psychiatry, and severe

mental illness treatment

From where data/document is obtainable

Sending email to the researchers

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

Requests for information will be reviewed by researchers and information will be sent if relevant to mental health research.

Comments