Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Cognitive Behavioral Group Psychotherapy on Cognitive Emotion Regulation Strategies of Adolescents with Youth Bipolar in Euthymic Phase

Protocol summary

Summary

(1) Objectives: The aim of this study is to examine the effect of cognitive behavioral group psychotherapy on emotion regulation strategies of adolescents with youth bipolar in Euthymic Phase. (2) Design: This research is an experimental study with “pre-test, post-test and follow-up with control group” design. (3) Setting and conduct: The sample size of this study estimated 70 persons that randomly 35 persons in control group and 35 persons in experimental group allocated. Instruments for data gathering are Demographic Questionnaire and Cognitive Emotion Regulation Questionnaire. (4) Participants including major eligibility criteria: Patients with diagnosis of early onset bipolar disorder; with age range 12 to 18 years old; have the ability to listen and sit in group therapy sessions; have the ability to respond to written questions; patients who are in the euthymic phase of bipolar disorder and according to the diagnosis of psychiatrist do not have any other physical illness or mental disorder. Exclusion Criteria including the patients who discharge before the completion of group therapy sessions; The absence of more than two sessions of group therapy. (5) Intervention: Firstly the pre-test will be done in both groups. The experimental group will attend 12 sessions of 90 minutes in group therapy. The control group will not receive any intervention in this duration. Then the post-test and follow up respectively one week and three months after intervention will be done in both groups and then the results of two groups will be compared with together. (6) The main outcome variable: Increasing use of adaptive cognitive emotion regulation strategies.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506286834N8**
Registration date: **2015-08-21, 1394/05/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-08-21, 1394/05/30

Registrant information

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Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Research Vice- Chancellor, Tabriz University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cognitive Behavioral Group Psychotherapy on Cognitive Emotion Regulation Strategies of Adolescents with Youth Bipolar in Euthymic Phase

Public title
The Effect of Cognitive Behavioral Group Psychotherapy on Cognitive Emotion Regulation Strategies of Adolescents with Youth Bipolar in Euthymic Phase
Purpose
Prevention
Inclusion/Exclusion criteria
Participants including major eligibility criteria: Patients with diagnosis of early onset bipolar disorder; with age range 12 to 18 years old; have the ability to listen and sit in group therapy sessions; have the ability to respond to written questions; patients who are in the euthymic phase of bipolar disorder and according to the diagnosis of psychiatrist do not have any other physical illness or mental disorder. Exclusion Criteria including the patients who discharge before the completion of group therapy sessions; The absence of more than two sessions of group therapy.
Age
From **12 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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 Tabriz University of Medical Sciences, Research Vice- Chancellor
Street address
Third floor, Central Building- No 2, Golgasht Street
City
Tabriz
Postal code
Approval date
2015-07-27, 1394/05/05
Ethics committee reference number
TBZMED.REC.1394.390

Health conditions studied

1

Description of health condition studied
Bipolar affective disorder
ICD-10 code
F31.7
ICD-10 code description
Bipolar affective disorder, currently in remission

Primary outcomes

1

Description
Cognitive emotion regulation strategies
Timepoint
Before intervention, one week and three months after finishing intervention
Method of measurement
Cognitive Emotion Regulation Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First, the pre-test will be done. Intervention group will receive 12 sessions group therapy. Then, the post-test and follow-up will be done. Finally, the differences of pre-test, post-test and follow-up are compared with each other.
Category
Prevention

2

Description
Control group: This group will not receive any intervention. The differences of pre-test, post-test and follow-up are measured and compared with each other.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Psychiatric Hospital
Full name of responsible person
Dr Arash Mohaggegi

Street address
Tabriz Razi Psychiatric Hospital, Elgoli Boulevard
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Vice- Chancellor, Tabriz University of Medical Sciences
Full name of responsible person
Dr Mohammad Reza Rashidi
Street address
Third floor, No 2 Building of Tabriz University of Medical Sciences, Golgasht Ave
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Vice- Chancellor, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty