

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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

###### Name

Hossein Ebrahimi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1475 1709

###### Email address

ebrahimih@tbzmed.ac.ir

##### 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

2015-07-27, 1394/05/05

**Ethics committee reference number**  
TBZMED.REC.1394.390

## 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

## 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**

Dr Hossein Ebrahimi

**Position**

PhD in nursing

**Other areas of specialty/work****Street address**

Psychiatric Nursing Group, Tabriz Nursing and Midwifery Faculty, South Shariati Street

**City**

Tabriz

**Postal code****Phone**

+98 41 3475 1709

**Fax****Email**

Ebrahimih@tbzmed.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Vegar Kazempour

**Position**

MS in Psychiatric Nursing, Student

**Other areas of specialty/work****Street address**

Psychiatric Nursing Group, Tabriz Nursing and Midwifery Faculty, South Shariati Street

**City**

Tabriz

**Postal code****Phone**

+98 41 4224 2449

**Fax****Email**

vegarkazempour@gmail.com

**Web page address****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*