

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of psycho-educational group therapy on internalized stigma of family caregivers of children with Bipolar mood disorder

#### Protocol summary

##### Summary

(1) Objectives: The aim of this study is to examine the effect of psycho-educational group therapy on internalized stigma of family caregivers of children with Bipolar mood disorder. (2) Design: This research is an experimental study with a "pre-test, post-test and follow-up with control group" design. (3) Setting and conduct: The sample size of this study estimated 88 persons that randomly 44 persons in control group and 44 persons in experimental group will allocated. Instruments for data gathering are Demographic Questionnaire and Modified Version of Internalized Stigma Questionnaire. (4) Participants will be chosen based on inclusion and exclusion criteria. (5) Interventions: Firstly the pre-test will be done in both groups. The experimental group will attend eight sessions of 90 minutes in psycho-educational group therapy. The control group will not receive any intervention in this duration. Then the post-test and follow up after one month will be done on both group. Finally the results of the two groups will be compared. (6) The main outcome variable: Reducing internalized stigma in receiving psycho-educational group therapy

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201605026834N10**

Registration date: **2016-12-17, 1395/09/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-17, 1395/09/27

##### Registrant information

##### Name

Hossein Ebrahimi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

ebrahimih@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Vice- Chancellor, Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-08-01, 1395/05/11

##### Expected recruitment end date

2017-02-01, 1395/11/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of psycho-educational group therapy on internalized stigma of family caregivers of children with Bipolar mood disorder

##### Public title

The effect of group therapy on stigma of family of children with Bipolar mood disorder

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Family caregiver who has not major Psychiatry problem; is first-degree relative with the patient; is the primary carer of the patient; lives in a

house with the patient; has at least ability to write and read; is at least 18 and up to 60 years old; and has obtained a minimum score of 42.5 in the stigma questionnaire in pretest; the diagnosis of his/her child is confirmed by a psychiatrist based on DSM V standards; his/her child is treated as outpatient; and his child is at least 8 and up to 18 years old. Exclusion criteria: Family caregiver has to decide to participate in other training program; dose not want to continue to participate in the study; experiences acute crisis such as divorce and death of loved one during the study; has history of substance abuse (according to self-reported); is graduated in the fields of medical sciences; has a history of serious physical illness, and known mental disorder; has absence more than one session from training sessions; his/her child hospitalized during the study; and his/her child has alcohol and drug dependency (according to the doctor or primary caregiver report).

#### **Age**

From **18 years** old to **60 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **88**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single 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**

2016-06-13, 1395/03/24

###### **Ethics committee reference number**

IR.TBZMED.REC.1395.268

### **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**

Internalized Stigmatization

##### **Timepoint**

Before, afer and one months after the intervention

##### **Method of measurement**

Internalized Stigmatization Scale of Mental Illnesses(ISSMI) Questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Firstly, the pre-test will be done. Intervention group will receive 8 sessions therapy by the researcher. 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 and post-test and follow up are measured and are 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 East Azarbayjan

**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 Tabriz

**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

**Name of organization / entity**  
Tabriz University of Medical Sciences

**Full name of responsible person**  
Somaye Janmohammadi

**Position**  
MS in Psychiatric Nursing, Student

### Other areas of specialty/work

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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Dr Hossein Ebrahimi

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PhD in nursing education

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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*