

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Effect of group psychoeducational programme on attitude toward mental illness in families of patients with schizophrenia and bipolar disorders: a randomized clinical trial

#### Protocol summary

##### Summary

(1) Objectives: The aim of this study is to determine the effect of group psychoeducational program on attitude toward mental illness in families of patients with schizophrenia and bipolar disorders. (2) Design: This research is a randomized clinical trial study (3) Setting and conduct: The sample size of this study has been estimated 80 families for schizophrenic patients group with 40 persons in control group and 40 persons in experimental group allocated randomly and 74 families for bipolar patients group with 37 families in control group and 37 families in experimental group allocated randomly. The data for this study will be gathered through Opinion about mental illnesses questionnaire. (4) Participants inclusion criteria: having willingness to participate in the study, literacy, being main caregiver of and responsible for patients with bipolar and schizophrenia disorders, not having a major psychiatric problem. (5) Intervention: First, the pretest will be done in both groups. The families of experimental group will receive 9 continuous 90-minutes psychoeducational sessions but the control group will not receive any intervention. Finally, the posttest will be done for both groups and the results will be compared. (6) The main outcome variable: Improving the attitude of families toward mental illness.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201509238359N2**

Registration date: **2015-10-02, 1394/07/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-10-02, 1394/07/10

##### Registrant information

###### Name

Farnaz Rrahmani

###### Name of organization / entity

Tabriz nursing and midwifery school

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1479 6770

###### Email address

frahmani@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Research center of psychiatry and behavioral sciences, Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-03-21, 1393/01/01

##### Expected recruitment end date

2014-09-23, 1393/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of group psychoeducational programme on attitude toward mental illness in families of patients with schizophrenia and bipolar disorders: a randomized clinical trial

##### Public title

Effect of psychoeducation on attitude towards mental

illness in families of patients with bipolar and schizophrenia disorders

### **Purpose**

Supportive

### **Inclusion/Exclusion criteria**

Inclusion criteria: having willingness to participate in the study; Being main caregiver of and responsible for patients with bipolar and schizophrenia disorders; Not having a major psychiatric problem; Literacy. Exclusion criteria: Not having willingness to participate in the study; Having physical or mental disorder that hinder the person's presence in the psychoeducation sessions.

### **Age**

No age limit

### **Gender**

Female

### **Phase**

N/A

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

*No information*

### **Sample size**

Target sample size: **80**

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

Randomized

### **Randomization description**

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

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

Random assignment of subjects into two groups: First, subjects' names will be written on paper and will be read randomly, then the subjects will be randomly divided into two groups of experimental and control.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences, Vice chancellor for research

##### **Street address**

Third floor, central building- No 2 of Tabriz University of Medical Sciences, vice chancellor for research, Goltasht street, Tabriz, Iran.

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2013-03-05, 1391/12/15

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

96162

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Attitude toward mental illness

#### **ICD-10 code**

Z63.7

#### **ICD-10 code description**

Other stressful life events affecting family and household

## **Primary outcomes**

### 1

#### **Description**

Attitude toward mental illness

#### **Timepoint**

Before intervention and after intervention

#### **Method of measurement**

Opinion about mental illnesses questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: First, the pretest will be done. The experimental group will participate in 9 sessions of psychoeducation managed by the researcher. During the sessions, the researcher will try to improve the attitude of the families toward the mental illness. Then, the posttest will be done and the results of the pretest and the posttest will be compared.

#### **Category**

Other

### 2

#### **Description**

Control group: This group will not receive any intervention. First, the pretest will be done. After completion of psychoeducation sessions for experimental group, the difference between pretest and posttest will be measured and compared with each other.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Razi hospital of Tabriz

##### **Full name of responsible person**

Farnaz Rahmani

##### **Street address**

Elgholi street, Razi hospital of Tabriz, Tabriz, Iran

**City**

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Fakhari Dehkharghani

**Street address**

Research Center of clinical psychiatric, Education unit, Elgholi street, Razi hospital of Tabriz, Tabriz, Iran

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

Farnaz Rahmani

**Position**

PhD student in nursing

**Other areas of specialty/work**

**Street address**

Elgoli street, Tabriz Razi Hospital, Tabriz, Iran.

**City**

Tabriz

**Postal code**

**Phone**

+98 413804486

**Fax**

**Email**

farnazrahmani58@gmail.com

**Web page address**

## Person responsible for scientific

## inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Farnaz Rahmani

**Position**

PhD student in nursing

**Other areas of specialty/work**

**Street address**

Elgoli street, Tabriz Razi Hospital, Tabriz, Iran.

**City**

Tabriz

**Postal code**

**Phone**

+98 41333804486

**Fax**

**Email**

farnazrahmani58@gmail.com

**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Farnaz Rahmani

**Position**

PhD student in nursing

**Other areas of specialty/work**

**Street address**

Elgoli street, Tabriz Razi Hospital, Tabriz, Iran.

**City**

Tabriz

**Postal code**

**Phone**

00

**Fax**

**Email**

fsrnazrahmani58@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*