

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Clinical trial of the effectiveness of group cognitive behavior therapy on improving drug compliance, quality of life and decreasing anxiety in female patients with bipolar mood disorder type I

#### Protocol summary

##### Summary

(1) Objectives: The aim of this study is to determine the effect of cognitive group therapy on the quality of life, anxiety and drug compliance in female patients with bipolar mood disorder type I hospitalized in psychiatric ward of Tabriz psychiatric center in 2012. (2) Design: This research is a quasi-experimental study with “pre-test and post-test with control group” design. (3) Setting and conduct: The sample size of this study has been estimated 70 persons with 35 persons in control group and 35 persons in experimental group allocated randomly. The data for this study will be gathered through Zung self report Anxiety scale, quality of life questionnaire (SF36) and health belief model questionnaire. (4) Participants inclusion criteria: being in the age range between 20 and 40, having at least high school degree, being in relative recovery phase of disorder and lack of brain injuries, mental retardation, substance abuse and epilepsy. (5) Intervention: First, the pre-test will be done in both groups. The experimental group will attend 12 sessions of 90-minutes group therapy, but the control group will not receive any intervention. Both of the groups will receive drug therapy according to the psychiatrist’s order. Finally, the post-test will be done in both of the groups and the results will be compared. (6) The main outcome variable: Improving the quality of life and drug compliance and decreasing anxiety.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112108359N1**  
Registration date: **2013-07-14, 1392/04/23**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-07-14, 1392/04/23

##### 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

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-10-12, 1392/07/20

##### Expected recruitment end date

2013-11-11, 1392/08/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of the effectiveness of group cognitive behavior therapy on improving drug compliance, quality of life and decreasing anxiety in female patients with bipolar mood disorder type I

**Public title**

The effectiveness of group cognitive behavior therapy on drug compliance, quality of life and anxiety in patients with bipolar mood disorder

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: Women patients with bipolar mood disorder type I hospitalized in women ward, being in the age range 20 to 40, having at least high school degree in education, not being in acute phase of illness, being in relative recovery phase of disorder and lack of brain injuries, mental retardation, substance abuse and epilepsy.

**Age**

From **20 years** old to **40 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not 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**

2011-06-14, 1390/03/24

**Ethics committee reference number**

5/4/2324

**Health conditions studied****1****Description of health condition studied**

Bipolar affective disorder

**ICD-10 code**

f31.1

**ICD-10 code description**

Bipolar affective disorder

**Primary outcomes****1****Description**

Anxiety

**Timepoint**

Before intervention, after intervention and every mount until 3 mounts

**Method of measurement**

Zung Self-Rating Anxiety Scale

**2****Description**

Quality of life

**Timepoint**

Before intervention, after intervention and every mount until 3 mounts

**Method of measurement**

Quality of life questionnaire (SF36)

**3****Description**

Drug compliance

**Timepoint**

Before intervention, after intervention and every mount until 3 mounts

**Method of measurement**

Health Belief Model questionnaire

**Secondary outcomes****1****Description**

Age

**Timepoint**

Pre-test

**Method of measurement**

Personal-social questionnaire

**2****Description**

Marital status

**Timepoint**

Pre-test

## Method of measurement

Personal-social questionnaire

### 3

#### Description

Illness duration

#### Timepoint

Pre-test

#### Method of measurement

Personal-social questionnaire

## Intervention groups

### 1

#### Description

Intervention group: First, the pre-test will be done. The experimental group will participate in 12 sessions of cognitive group therapy managed by the researcher. During the sessions, the researcher will try to improve the insight of the patients toward the drug compliance and solve their problems relating to their illness. Then, the post-test will be done and the results of the pre-test and the post-test will be compared.

#### Category

Other

### 2

#### Description

Control group: This group will not receive any intervention. Both of the groups will receive drug therapy. The difference of the quality of life, anxiety and drug compliance of the pre-test and the post-test will be measured and compared with each other.

#### Category

Treatment - 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

Vice chancellor for research, Tabriz University of Medical Sciences

##### Full name of responsible person

Mohammad Reza Rashidi

#### Street address

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

Vice chancellor for research, 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

Razi hospital of Tabriz University of Medical Sciences

##### Full name of responsible person

Farnaz Rahmani

##### Position

Master of sciences in psychiatric nursing, nurse

##### Other areas of specialty/work

##### Street address

Elgoli street, Tabriz Razi hospital, Tabriz, Iran.

##### City

Tabriz

##### Postal code

##### Phone

+98 41138044869

##### Fax

+98 41 1380 3351

##### Email

frahmani@tbzmed.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Razi hospital of Tabriz University of Medical Sciences

##### Full name of responsible person

Farnaz Rahmani

##### Position

Master of sciences in psychiatric nursing

##### Other areas of specialty/work

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**Other areas of specialty/work**

**Street address**

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**City**

## 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*