

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

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Person responsible for scientific inquiries

Contact

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Position

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Person responsible for updating data

Contact

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Full name of responsible person

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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