

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of group psycho-education on quality of life, relapse rate, and treatment compliance in patients with bipolar mood disorder- Type I

Protocol summary

Summary

This is a 6 month randomized waiting-list and controlled clinical trial examines the adjuvant effect of psycho-education for treating and the relapse prevention of patients with bipolar disorder- type I. Diagnosis are made using DSM-IV-TR. Patients in the treatment group receive a structured psycho-education program in 9 sessions. The patients in the controlled group receive an unstructured program. The waiting-list group will not be psycho-educated during this trial. Assessments occur three times including pre-intervention, 3 months after the intervention, and 6 months after the intervention. The patients are evaluated using Young Mania Rating Scale, Hamilton Depression Rating Scale, and short-form of WHO-Quality of life inventory.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305213930N23**

Registration date: **2013-06-13, 1392/03/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-13, 1392/03/23

Registrant information

Name

Ahmad Ghanizadeh

Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 3070

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ghanizad@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-10-01, 1391/07/10

Expected recruitment end date

2014-11-20, 1393/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of group psycho-education on quality of life, relapse rate, and treatment compliance in patients with bipolar mood disorder- Type I

Public title

Efficacy of group psycho-education on patients with bipolar mood disorder- Type I

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosed Bipolar Disorder-type I in accordance with DSM-IV-TR, aged 18 to 50 years, and being euthymic at the time of enrollment. Exclusion criteria: patients with acute phase of mania, and active current substance use.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 45

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2012-09-30, 1391/07/09

Ethics committee reference number

301/130/92/3

Health conditions studied

1

Description of health condition studied

Bipolar mood disorder

ICD-10 code

F30-39

ICD-10 code description

Mood Disorder

Primary outcomes

1

Description

Hamilton Depression Rating Scale

Timepoint

baseline, 3 months, and 6 months

Method of measurement

Interview

2

Description

Young Mania Rating Scale

Timepoint

baseline, 3 months, and 6 months

Method of measurement

Interview

Secondary outcomes

empty

Intervention groups

1

Description

Waiting-list

Category

Other

2

Description

Placebo

Category

Treatment - Other

3

Description

Placebo

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Center for Psychiatry and Behavioral Sciences, Shiraz University of Medical Sciences

Full name of responsible person

Ahmad Ghanizadeh

Street address

Hafez Hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical sciences

Full name of responsible person

Gholam Reza Hatam

Street address

Hafez Hospital

City
Shiraz

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Iran University of Medical Sciences

Full name of responsible person
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Position
Psychologist, PhD

Other areas of specialty/work

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Person responsible for updating data

Contact

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