

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of group psycho-education program on bipolar patients' adherence to drug, insight and quality of life

Protocol summary

Summary

This study aimed to determine the efficacy of group psycho-education on medication adherence, insight and quality of life in patients with bipolar disorder. In this study, the statistical samples included patients with bipolar disorder in Zanjan. The samples were selected from patients who referred to psychiatric private clinics and governmental centers of Zanjan University of Medical Sciences, Beheshti hospital. Sampling was based on availability. There were several inclusion criteria for in this study: having the euthymic mood during the study and being diagnosed as bipolar disorder based on diagnostic interview. The exclusion criteria of the study was being at the acute phase of the disease or being an active drug abuser. After checking the inclusion and exclusion criteria 20 patients with bipolar disorder were selected and categorized into two groups: the experimental group (n=10), the control group (n=10). The content of psycho-educational group program consisted of bipolar disorder definition and its causes, an introduction to the symptoms of mania and hypomania, the process and prognosis of the disease, medications for treatment of mania and depression, learning early identification of disorder. The control group continued their routine treatment. Primary outcome measure was adherence to drug. Secondary outcome measures were insight and quality of life. Medication adherence, Quality of life and insight scale of the Two groups were evaluated before and After the intervention, One month after the intervention using Morisky Medication Adherence Scale, Short form of quality of life and Mood Disorder Insight Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061928533N1**

Registration date: **2016-08-13, 1395/05/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-13, 1395/05/23

Registrant information

Name

Arezu Nahid Sahlan

Name of organization / entity

Medical Science of Zanjan

Country

Iran (Islamic Republic of)

Phone

+98 41 3266 4793

Email address

arezu.nahid@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Social Determinants of Health Research Center Valiasr Zanjan hospital

Expected recruitment start date

2016-04-29, 1395/02/10

Expected recruitment end date

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of group psycho-education program on bipolar patients' adherence to drug, insight and quality of life

Public title

Effectiveness of psychoeducation program in bipolar patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : being diagnosed as bipolar disorder based on diagnostic interview and SCID-I/CV test results. Being in the age range of 18 to 50, having the euthymic mood during the study (score less than or equal to 7 for Hamilton scale and score less than or equal to 6 for Young Mania scale). Exclusion criteria : being at the acute phase of the disease or being an active drug abuser, having mental retardation, having the full criteria for Schizophrenia diagnosed by psychiatrist and according to SCID-I.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Postal code**

45156-13191

Approval date

2016-05-31, 1395/03/11

Ethics committee reference number

zums.rec.1395.61

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

bipolar disorder

ICD-10 code

F31.7

ICD-10 code description

Bipolar affective disorder, currently in remission

2**Description of health condition studied**

bipolar disorder

ICD-10 code

F31.7

ICD-10 code description

Bipolar affective disorder, currently in remission

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

Adherence to drug

Timepoint

before therapy, after therapy, after a month

Method of measurement

morisky medication adherence scale

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

insight and quality of life

Timepoint

before therapy, after therapy, a month after therapy

Method of measurement

mood disorder insight scale, world health organization questionnaire

Secondary Ids**1****Registry name**

Zums.ac.ir

Secondary trial Id

Zums.REC.1395.61

Registration date

1395-11-21, 777/01/-849

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of University of Medical Sciences.

Street address

Zanjan University Of Medical Science, Azadi Blvd,
Zanjan

City

Zanjan

Intervention groups**1****Description**

Group 1: A psycho-educational program was conducted for the psycho-educational group(Combined intervention psychoeducation Plus Medication) during 5 weekly sessions.

Category

Other

2

Description

group (2): Pharmacotherapy They received as usual treatment (Medication)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Beheshti Hospital

Full name of responsible person

Arezu Nahid

Street address

Zanjan Ark- the martyr Beheshti Hospital in Zanjan

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Medical Science Of Zanjan

Full name of responsible person

Vice chancellor for research, Zanjan University Of Medical Science

Street address

Zanjan University Of Medical Science, Azadi Blvd, Zanjan

City

zanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Medical Science Of Zanjan

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

Zanjan University of Medical Science

Full name of responsible person

Arezu Nahid sahan

Position

masters student in clinical psychology

Other areas of specialty/work

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>