

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

the influence of family group psycho-education on relapse rate and length of stay in hospital in hospitalized Patients with bipolar mood disorder type I

Protocol summary

Summary

The purpose of the study is to assess the effectiveness of family group Psychoeducation on the reduction of recurrence in patients with bipolar disorder. In this study, patients with bipolar , randomly divided into two groups. Both groups of patients in Qazvin hospitals are selected. A sample of 64 participants, which will be divided equally into two groups. Of all patients Inventory Beck and Young Mania (depending on the phase of disease) and the Family Questionnaire will be taken. The experimental group received group family psychoeducation .Psychoeducation is done to the family intervention group. Number of sessions: 4 sessions on a weekly basis. Each session will be held for 60 minutes. Themed sessions such as training in line with the nature of bipolar disorder; early signs of relapse; treatment of diseases; implementation strategies at the time of relapse; Introduction to reassertion of continued support systems ; treatment will be provided; anger management education; problem solving. Medical treatment will not be affected durinf the study .After at least 6 months and a maximum of 9 months follow-up , will be compared the two groups in terms of recurrence, number of hospitalization, severity of symptoms, length of stay in hospital , family adaptation . family group psycho-education on these issues will be evaluated.The inclusion criteria were: diagnosis of bipolar disorder based on structured psychiatric interview ; the patient's life in a family environment and having at least one family member to attend training sessions ; aged 18 to 65 years ; informed consent. Exclusion criteria: lack of consent from the patient or the patient's family to participate in research project ; psychological training for families or patients in the control group, in the course of the study ; the absence of key members of the family in even one session of training.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091612018N5**
Registration date: **2016-10-10, 1395/07/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-10, 1395/07/19

Registrant information

Name

Hossein Javdani

Name of organization / entity

Tabriz university of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the influence of family group psycho-education on relapse rate and length of stay in hospital in hospitalized Patients with bipolar mood disorder type I

Public title

Effectiveness of family group Psychoeducation on the reduction of recurrence in patients with bipolar disorder

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria were: diagnosis of bipolar disorder based on structured psychiatric interview (SCID), according to diagnostic criteria revised fourth edition of Diagnostic and Statistical Manual of Mental Disorders ; the patient's life in a family environment and having at least one family member to attend training sessions ; aged 18 to 65 years ; informed consent. Exclusion criteria: lack of consent from the patient or the patient's family to participate in research project ; psychological training for families or patients in the control group, in the course of the study ; the absence of key members of the family in even one session of training.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

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

Ethics Committee of Qazvin University Medical Science

Street address

Qazvin University of Medical Sciences , Shahid Bahonar Blvd

City

Qazvin

Postal code

Approval date

2015-09-30, 1394/07/08

Ethics committee reference number

IR.QUMS.REC.1394.136

Health conditions studied

1

Description of health condition studied

Bipolar affective disorder

ICD-10 code

F 31

ICD-10 code description

Bipolar affective disorder

Primary outcomes

1

Description

Recurrency

Timepoint

9 months after the intervention .

Method of measurement

the number of hospitalization during follow up .

2

Description

the number of hospitalization days .

Timepoint

9 months after intervention .

Method of measurement

Review of hospital records during follow up .

3

Description

Depression

Timepoint

Baseline and 9 month after intervention .

Method of measurement

Beck depression inventory

4

Description

mania

Timepoint

Baseline and 9 months after the intervention .

Method of measurement

Young Mania Scale

Secondary outcomes

1

Description

Family adaptation

Timepoint

Baseline and 9 months after the intervention.

Method of measurement

Mac Master questionnaire

Intervention groups

1

Description

Control group: no intervention

Category

N/A

2

Description

Intervention group:Psychoeducation to family patients .
Number of sessions: 4 ; weekly basis ; time each session
60 minutes.

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital

Full name of responsible person

Dr Marzieh Javani

Street address

22 Bahman Hospital , Rah-ahan avenue , Street
Parastar

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of
Medical Sciences

Full name of responsible person

Taghi Naserpoor

Street address

Qazvin University of Medical Sciences , Shahid
Bahonar Blvd

City

Qazvin

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, Qazvin 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

Qazvin University of Medical Science

Full name of responsible person

Dr Marzieh Javani

Position

Resident of Psychiatry

Other areas of specialty/work

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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