

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between efficacy of family- center and patient- center psycho-education model on drug compliance in patients with mental disorders

Protocol summary

Summary

Objectives: Comparison of family- center and patient- center psycho- education model on drug compliance in patients with mental disorders in Bushehr. Design: Randomized, clinical trial. Setting and conduct: Fifty schizophrenic patients and fifty patients with bipolar disorder were randomly divided into two subgroups separately. One subgroups of patients with schizophrenia and bipolar disorder will be trained through family- center psycho- education model and other subgroups of these patients will be trained through patient- center psycho- education model. Inclusion criteria includes age between 18- 60 years old; diagnosis of schizophrenia and bipolar disorder; according to BMQ questionnaire (Beliefs about medicines questionnaire), drug compliance score less than 5. Exclusion criteria includes start the acute phase of the disease; not participation in more than two training sessions. Interventions: In the first intervention group, patients and one of their family members will be trained through psycho- education model and in the other group, just patients will be trained through psycho- education model. In this model, six weekly sessions will be explained about disorder definition and its causes, the process and prognosis, medications and early identification of disorder. Before, after and one month later Patients' drug compliance will be evaluated by BMQ questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607188473N6**
Registration date: **2017-01-22, 1395/11/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-22, 1395/11/03

Registrant information

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2017-01-19, 1395/10/30

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between efficacy of family- center and patient- center psycho-education model on drug compliance in patients with mental disorders

Public title

Effect of psycho-education model on drug compliance in patients with mental disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria includes age between 18- 60 years old; diagnosis of schizophrenia and bipolar disorder; according to BMQ questionnaire (Beliefs about medicines questionnaire), drug compliance score less than 5. Exclusion criteria includes start the acute phase of the disease; not participation in more than two training sessions

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Bushehr University of Medical Sciences

Street address

Bushehr University of Medical Sciences, Sabz Abad,
Bushehr, Iran

City

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7518759577

Approval date

2016-05-16, 1395/02/27

Ethics committee reference number

IR.BPUMS.REC.1395.22

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

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Drug compliance

Timepoint

Before the intervention; after the intervention; one months after the intervention

Method of measurement

Beliefs about medicines questionnaire (BMQ)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: in this group, patient- center psycho-education model will be used in six 90- 120 minute training sessions during six consecutive weeks. In this model just patient will be trained about disorder definition and its causes, the process and prognosis, medications and early identification of disorder.

Category

Other

2

Description

Intervention: in this group, family- center psycho-education model will be used in six 90- 120 minute training sessions during six consecutive weeks. In this model patients and one of their family members will be trained about disorder definition and its causes, the process and prognosis, medications and early identification of disorder.

Category

Other

Recruitment centers

1

Recruitment center

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Person responsible for scientific inquiries

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Sponsors / Funding sources

1

Sponsor

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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, Bushehr 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

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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