

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Impact of a systematic intervention program on quality of life, relapse prevention and medication compliance in patients with bipolar disorder

#### Protocol summary

##### Summary

Bipolar disorder is one of ten most debilitating diseases in the world. In addition to posing a burden on the healthcare system leads to a lessened quality of life and increased occupational accidents amongst its sufferers. This study demonstrates the effectiveness of psychoeducation intervention along with a patient support system in management of this disorder. This study was done on Bipolar patients. Inclusion criteria were being in spectrum of 18-60 year old; past history of 2 episodes during 2 years or 3 episodes during 5 years and being in euthymic phase. Exclusion criteria included age >60 years or <18 years old; less than 2 episodes during 2 years or less 3 episodes during 5 years; and being in acute phase or with sever residual symptoms . In this trial, a total of 108 patients, divided equally into two groups, were randomly assigned to receive pharmacotherapy alone treatment (control group) and psychoeducation along with pharmacotherapy (intervention group) for a two year period. "control" group, throughout the research period, only received pharmacological therapy by referring to the health carer of their choosing. Each group was evaluated, once every 6 months for a period of 18 months, in the areas of "quality of life", "symptoms of relapse", "pharmacotherapy compliance" and "number of hospital admission for recurrence of bipolar disorder".

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201202159028N1**  
Registration date: **2012-08-27, 1391/06/06**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-08-27, 1391/06/06

##### Registrant information

###### Name

Arvin Hedayati

###### Name of organization / entity

Shiraz University Of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1620 6747

###### Email address

hedayatia@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Psychiatric Research Center of Shiraz University Of Medical Science

##### Expected recruitment start date

2009-12-22, 1388/10/01

##### Expected recruitment end date

2010-07-21, 1389/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Impact of a systematic intervention program on quality of life, relapse prevention and medication compliance in patients with bipolar disorder

##### Public title

Impact of a psycho-education on patients with bipolar disorder

##### Purpose

Supportive

## Inclusion/Exclusion criteria

inclusion criteria : 18-60 year old; past history of 2 episodes during 2 years or 3 episodes during 5 years; in euthymic phase. exclusion criteria: >60 years or <18 years old; less than 2 episodes during 2 years or less 3 episodes during 5 years; in acute phase or with severe residual symptoms

## 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: **96**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double 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 Shiraz medical university

##### Street address

Shiraz medical university

##### City

shiraz

##### Postal code

#### Approval date

2010-12-26, 1389/10/05

#### Ethics committee reference number

2871

## Health conditions studied

### 1

#### Description of health condition studied

bipolar mood disorder

#### ICD-10 code

F31

#### ICD-10 code description

Bipolar affective disorder

## Primary outcomes

### 1

#### Description

quality of life. medication adherence. recurrence.admission

#### Timepoint

6, 12 and 18 months after beginning of study

#### Method of measurement

WHO QOL BREF. hamilton depression scale. Bech Rafaelsen mania scale. Medication adherence Rating scale

## Secondary outcomes

### 1

#### Description

severity of depression and mania

#### Timepoint

at 6, 12 and 18 months after beginning of study

#### Method of measurement

Hamilton depression scale. Bech Rafaelsen mania scale

## Intervention groups

### 1

#### Description

Patients in intervention group, received standard pharmacotherapy for BpD and also enrolled for simple individual psychoeducation. Program consisted of 8 sessions each consisting of a 50 minute session per week of a short form of psychoeducation course, derived from studies of Colom, F. and Vieta, E. (19). Sessions of psychoeducation were performed by a psychiatry resident who was blinded to treatment. All psychoeducation treatment sessions for all patients were performed by the same resident who conducted a one-on-one session with each individual patient. Psychoeducation programs and discussions were presented to the patients in the following format: Session 1: Understanding BpD. and its aetiology. Session 2: Familiarisation with symptoms of mania and hypomania. Session 3: Understanding signs of depression and other psychological episodes. Session 4: Awareness of causes and prognosis. Session 5: Education about the function, types and adverse side effect of mood stabiliser medication. Session 6: Functions, types and adverse effects of antimanic and antidepressant medications. Patients also receive information about the risk of discontinuation of these medications. Session 7: Learning how to detect any future episodes of relapse. Session 8: Strategies and plans ought to be taken upon early detection of symptoms and self directed to new situations. These 8 weekly scheduled sessions were conducted face to face in the clinic of psychology at Hafez Hospital. The first 10 minutes of each sitting was allocated to establishing rapport with the patient, and a short question and answer session. During this period, the patients were asked to explain, in their own words,

their understanding of all presented material. Any misconstrued discussed and explained in detail. After first 10 minutes the researcher gave all relevant information in layman language about the particular topics for 40 minutes. The strategies and plans for early detections of symptoms discussed. After 8 sessions of face to face simple individual education, intervention continued by way of scheduled monthly telephone contact to remind patients of their next appointment. Each telephone contact consisted of a 10-minute question and answer session where the patient's queries were thoroughly responded to. Follow-up telephone contact for each patient was then scheduled for the subsequent 18 months.

**Category**

Lifestyle

**2****Description**

Patients who were randomised in the control group were continuing standard pharmacotherapy by their psychiatrists of choice

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hafez Hospital

**Full name of responsible person**

Arvin Hedayati MD

**Street address**

Iran , Shiraz, shahid beheshti town, ferdous avenue,

**City**

Shiraz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz medical university

**Full name of responsible person**

M. H Dabaghmanesh MD

**Street address**

Shiraz University Of Medical Science

**City**

shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz medical university

**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**

Shiraz University Of Medical Science

**Full name of responsible person**

Ali Javadpour MD

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Psychiatric Department , Hafez Hospital , Shiraz , Iran

**City**

Shiraz

**Postal code****Phone**

+7 116271531

**Fax****Email**

javadpoura@sums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University Of Medical Science

**Full name of responsible person**

Ali Javadpour MD

**Position**

Assistant professor

**Other areas of specialty/work****Street address**

Psychiatric department, Hafez Hospital , Shiraz, Iran

**City**

Shiraz

**Postal code****Phone**

+7 116271531

**Fax****Email**

javadpoura@sums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University Of Medical Science

**Full name of responsible person**

Arvin hedayati MD

**Position**

Psychiatric Resident

**Other areas of specialty/work****Street address**

Psychiatric Department, Hafez Hospital, Shiraz, Iran

**City**

Shiraz

**Postal code**

Iran

**Phone**

00

**Fax****Email**

hedayatia@sums.ac.ir

**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*