Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 disorderThis 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 2episodes 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 2episodes during 2 years or less 3 episodes during 5 years; in acute phase or with sever 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 Commite 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.admision

Timepoint
6 ,12 and 18 months after begining 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 T 12 and 18 months after begining of study

Method of measurement
Hamilon 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

Assistent 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

Shirazl 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