

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effectiveness of supportive-expressive dynamic psychotherapy in improving the treatment outcome of Bipolar Spectrum Disorders in Male Hospitalized Patients

Protocol summary

Study aim

Supportive

Design

In this randomized controlled trial, 36 men with bipolar disorder who met the inclusion criteria and admitted to the psychiatric ward were selected. They were diagnosed with bipolar disorder based on DSM-5 criteria and a clinical psychiatrist's diagnosis and selected voluntary using available sampling method. Participants were randomly assigned to the two experimental and control groups of 18.

Settings and conduct

36 patients from the psychiatric ward of men in Medical University hospital (Khorshid) of Isfahan, after acute phase of illness and discharge from the emergency department of psychiatry and transfer to the psychiatric ward of the hospital were selected by Block randomization method and then enrolled to the study.

Participants/Inclusion and exclusion criteria

1- Having bipolar mood disorder based on psychiatrist's diagnosis; 2- Hospitalized; 3. Normal IQ.4. Male gender; 5. Lack of co-morbid serious physical and organic problems (Including sensory impairments such as deafness and blindness, severe physical disabilities); 6. No cognitive impairment that interferes with understanding and participating in treatment; 7.The absence of other serious psychiatric disorders (e.g.psychotic symptoms , anxiety disorders,...)

Intervention groups

Patients in the treatment group were treated with supportive-expressive psychotherapy in addition to the maintenance phase drug treatment.The control group received only standard drug treatment and didn't receive no other intervention. Intervention sessions based on existing protocols of supportive psychotherapy-expressive therapy were held in weekly 16 sessions of 30-minutes totally for four months.

Main outcome variables

Bipolar Disorders rating scale (BDRS), Relapse Rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180716040485N1**

Registration date: **2019-09-15, 1398/06/24**

Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**

Update count: **0**

Registration date

2019-09-15, 1398/06/24

Registrant information

Name

Alireza Bornamanesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3773 6684

Email address

Bornamanesh@miau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-01, 1397/12/10

Expected recruitment end date

2019-09-01, 1398/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation the effectiveness of supportive-expressive dynamic psychotherapy in improving the treatment outcome of Bipolar Spectrum Disorders in Male Hospitalized Patients

Public title
Evaluation the effect of supportive-expressive dynamic psychotherapy in Bipolar Spectrum patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Having bipolar mood disorder based on psychiatrist's diagnosis Hospitalized Normal IQ. Male gender. Lack of co-morbid physical and organic serious problems (Including sensory impairments such as deafness and blindness, severe physical disabilities) No cognitive impairment that interferes with understanding and participating in treatment The absence of other serious psychiatric disorders (e.g.psychotic symptoms , anxiety disorders,...)
Exclusion criteria:
 The patient's unwillingness to continue the participation in study Absence for more than one session and the absence in the session considered as compensated session Hospital discharging

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method was simple and performed centrally using random numbers table. Each patient's record was assigned a number from 1 to 36 and then randomly assigned to intervention and control groups. Paired numbers were assigned to the control group and individual numbers to the intervention group. In total, 36 patients were divided into two groups of 18.

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

Institutional Research Ethics Committee Islamic Azad University- Shiraz Branch

Street address

5 km after Sadra Highway

City

Shiraz

Province

Fars

Postal code

74731 71987

Approval date

2019-02-25, 1397/12/06

Ethics committee reference number

IR.IAU.SHIRAZ.REC.1398.002

Health conditions studied

1

Description of health condition studied

Bipolar Mood Disorders

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

Bipolar disorder level

Timepoint

BDRS scores at the beginning of the study (maintenance phase), immediately after the completion of psychological interventions 1 month, 3 months and 6 months after the start of the study in the supportive-psychotic recipient group, along with drug therapies

Method of measurement

The BDRS and its subscales in the sample of Iranian patients have a construct validity, ownership, distinction, and diagnosis that can be used in surveying and clinical trials.

2

Description

Relapse Rate

Timepoint

1 Month after intervention, 3 Month After Interventions , 6 Month after Intervention

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Adult male patients with bipolar disorder treated under medical treatment

Category

Diagnosis

2

Description

Intervention group: The men patients with bipolar disorder received drug treatment in addition to supportive expressive psychotherapy. This was an insight-based psychotherapy model and a selective psychotherapy for treating patients that had adequate ego strength, but for some reason should not or could not be enroll in long term psychoanalysis sessions. The main approach of therapy was insight based. The patient's response, however, was depend on factors such as the creating judgment free and supportive and emphatic which was mostly depending on factors such as the relationship between the therapist and the patient. The treatment lasted from 12 to 25 sessions in terms of the length of the treatment, and usually the number of sessions was once a week in the early stages of treatment, but when we entered the main phase of the treatment (middle phase), the number of sessions was twice a week.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Men Inpatients Psychiatry section at Khorshid complex at Medical University of Isfahan

Full name of responsible person

Alireza Bornamanesh

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Ostandari St, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University (IAU)

Full name of responsible person

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Grant name

No Grant

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University (IAU)

Proportion provided by this source

2

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Alireza Bornamanesh

Position

Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable