

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the efficacy of drug therapy with cognitive-behavioral therapy with the drug in reducing the symptoms and sings of type 2 bipolar disorder.

Protocol summary

Study aim

Identify the signs and symptoms that drug medication or cognitive-behavioral therapy with the drug has in reducing or improving them.

Design

Twenty patients with type 1 bipolar mood disorder who were admitted to the psychiatric ward were selected. They were randomly (A random number table) assigned to TAU (N=10) or CBT with TAU (N=10). Each group will be receive its own therapy.

Settings and conduct

Intervention and control groups consist of type 1 bipolar patients that were admitted to the psychiatric ward of Fatemi Hospital in Ardebil . At first, bipolar patients were randomly assigned to two groups of drug therapy(control group) and cognitive-behavioral therapy with drug(Intervention group).

Participants/Inclusion and exclusion criteria

Including critria: -Age minimum 18 and maximum 50 years ; Minimum education third grade middle school; Minimum standards DSM-V criteria; First episode of disease Excluding critria: Having substance abuse and active thoughts of suicide; psychotic disorder and OCD and personality disorder; impulse control disorder and aggression; pregnant; history of any psychiatric treatment in the past 6 months

Intervention groups

The drug treatment group will receive treatment as usual (TAU) treatment. And in the patients of the cognitive behavioral therapy group along with the drug receive TAU treatment and cognitive-behavioral therapy for 8 weeks based on the JC Wright method.

Main outcome variables

High mood; sexual interests; sleep; thought content; aggressive behavior; irritability; speech impairment; appearance; insight; motor activity; speech speed

General information

Reason for update

Acronym

none

IRCT registration information

IRCT registration number: **IRCT20170103031741N2**

Registration date: **2018-09-11, 1397/06/20**

Registration timing: **retrospective**

Last update: **2018-09-11, 1397/06/20**

Update count: **0**

Registration date

2018-09-11, 1397/06/20

Registrant information

Name

nikou salmani aghdam

Name of organization / entity

Ardebil University of medical sience

Country

Iran (Islamic Republic of)

Phone

+98 45 3333 1797

Email address

ni.salmani@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Educational Assistant University of Medical Sciences
Ardabil

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2018-09-01, 1397/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of drug therapy with cognitive-behavioral therapy with the drug in reducing the symptoms and signs of type 2 bipolar disorder.

Public title

The effect of cognitive behavioral therapy (CBT) for reducing signs and symptoms of bipolar disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age minimum 18 years and maximum 50 years Minimum education third grade middle school Minimum standards DSM-V criteria for the diagnosis of bipolar disorder type People who experience a first episode of disease Chronic patients who had at least 2 weeks of discontinuation And a new episode of recurrent disease and had been hospitalized.

Exclusion criteria:

Having substance abuse Having active thoughts of suicide Having any comorbidity disorder accompanied by a psychotic clinical presentation. Having OCD Having any personality disorder. Having impulse control disorder and aggression. Any pregnant. History of any psychiatric treatment in the past 6 months. Hospitalized patients have a history of drug treatment without discontinuing the drug.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

A sample of bipolar patients is a type of admission in the psychiatric ward in an accessible manner, of which 20 will be contributed. Patients with Bipolar Mood Disorder in the department (based on psychiatric diagnosis) are divided into two groups of drugs and cognitive-behavioral therapy with the drug randomly. The accident method will be simple. A random number table is a collection of numbers that are generated without a specific pattern or order and completely randomized. To use a random number table, we first set the table numbers to read, for example, top, bottom, left, or right. The second default considering numbers for different groups for example, pair numbers for intervention A (drug treatment group) and individual numbers for intervention B (cognitive behavioral therapy group with medication). -Randomization: Individual. -Randomization

Tool: Random Number Tables. -Allocation concealment: Numbered drug containers

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**

Ethical Committee of Ardabil University of Medical Sciences

Street address

Ardebil University of medical sciences.,University Square.,University Avenue.,Ardebil

City

Ardebil

Province

Ardabil

Postal code

56189-85991

Approval date

2016-10-31, 1395/08/10

Ethics committee reference number

IR.ARUMS.REC.1395.57

Health conditions studied**1****Description of health condition studied**

Bipolar Mood Disorder type one

ICD-10 code

Chapter V

ICD-10 code description

F31

Primary outcomes**1****Description**

High Mood

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

Yang Mania Scale Response; Hamilton Test

2

Description

Sexual interests

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

Yang Mania Scale Response; Hamilton Test

3

Description

Sleep

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

Yang Mania Scale Response; Hamilton Test

4

Description

Thought content

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

Yang Mania Scale Response; Hamilton Test

5

Description

Aggressive behavior

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

Yang Mania Scale Response; Hamilton Test

6

Description

Irritability

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

Yang Mania Scale Response; Hamilton Test

7

Description

Speech impairment

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

Yang Mania Scale Response; Hamilton Test

8

Description

Appearance

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

Yang Mania Scale Response; Hamilton Test

9

Description

Insight

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

Yang Mania Scale Response; Hamilton Test

10

Description

Motor activity

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

Yang Mania Scale Response; Hamilton Test

11

Description

Speech speed

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

Yang Mania Scale Response; Hamilton Test

Secondary outcomes

1

Description

Quality of life

Timepoint

At the beginning of the study and 2 months after the intervention

Method of measurement

FS36 Score

Intervention groups

1

Description

Intervention group : will be receive cognitive-behavioral therapy (12 sessions,Based on JC Wright method) with a common drug treatment such as sodium valproate (15mg/kg/Daily, PO) and lithium(400mg daily,PO) for 2 month .

Category

Behavior

2

Description

Control group: will be receive a common drug treatment such as sodium valproate (15mg/kg/Daily, PO) and lithium(400mg daily,PO) for 2 month .

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi hospital

Full name of responsible person

Dr Mehryar Nadermohammadi

Street address

Fatemi hospital.,Emam khomeyni AVE.,Isghah sareyn., Ardebil

City

Ardabil

Province

Ardabil

Postal code

5614733775

Phone

+98 45 3323 2520

Fax

+98 45 3323 2670

Email

fatemi@arums.ac.ir

Web page address

<http://www.arums.ac.ir/fatemi/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Habibzadeh

Street address

University ave., ardebil

City

Ardebil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3352 2247

Fax

+98 45 3352 2196

Email

info@arums.ac.ir

Web page address

<http://arums.ac.ir/fa>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Ardabil University of Medical Sciences

Full name of responsible person

Dr Mehryar Nadermohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Fatemi Hospital., Emam Khomeyni Ave., Isghah Sarey.,Ardebiln

City

Ardabil

Province

Ardabil

Postal code

5614733775

Phone

+98 45 3324 2400

Fax

Email

m.nadermohammadi@arums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Parviz Molavi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Fatemi Hospital., Emam Khomeyni Eve., Isghah
Sareyn., Ardebil

City

Ardabil

Province

Ardabil

Postal code

5614733775

Phone

+98 45 3323 2520

Fax

Email

fatemi@arums.ac.ir

Web page address

Email

NI.SALMANI@ARUMS.AC.IR

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Total data after unidentifiable people as SPSS can be shared.

When the data will become available and for how long

Six months later print the results.

To whom data/document is available

Researchers working in academia and academia.

Under which criteria data/document could be used

In order to investigate narrative and data validation.

From where data/document is obtainable

Fatemi Hospital, Department of Psychiatry, proprietary files of this study.

What processes are involved for a request to access data/document

Applying for access to project documentation, apply to the hospital's research council and then issue permission to access files and data.

Comments

FF

Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Nikou Salmani Aghdam

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Ardabil University Ave

City

Ardebil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3352 2247

Fax