Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Iran (Islamic Republic of)

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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 sings 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.,Ardebill
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 Mehyar Nadermohammadi

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Sponsors / Funding sources

1

Sponsor

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Ardabil University of Medical Sciences

Full name of responsible person
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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
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

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Person responsible for updating data

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Full name of responsible person
Nikou Salmani Aghdam

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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
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