

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effect of group cognitive behavioral therapy on mood symptoms and temptation to substance use in male patients with bipolar disorder and substance dependence.

Protocol summary

Study aim

Determining the effect of GCBT on mood symptoms and temptation to use Substances in male patients with bipolar disorder and substance dependence.

Design

The clinical trial has a control group, randomized by random block method, one-way blind, the total of intervention and control groups are 40 people.

Settings and conduct

GCBT sessions are held in the classrooms of the psychiatry departments of Sinai Hospital in two separate closed groups of 10 people (20 people in total) in two 1.5-hour sessions per week. The people who completed the questionnaires (by interview method) and analyzed the data were blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the diagnosis of bipolar disorder has been confirmed by a psychiatrist; substances dependence; ability to communicate and answer questionnaires; literate in reading and writing; consent to participate in the study; receive usual medical care and treatment; not having a physical or mental disability; not having another psychiatric disorder; not participating in similar psychotherapy. Exclusion criteria: entering the acute phase of the disease; absence from more than 2 group therapy sessions.

Intervention groups

Eight sessions of GCBT are conducted as follows: 1: Introduction, statement of goals and structure of sessions. 2: getting to know the common cognitive errors in manic and depressive periods 3: Dealing with temptation. 4: Refusal skills, managing social situations and strengthening courage. 5: Making wise decisions 6: problem solving, anger control, stress management and emotion control. 7: modification of lifestyle, management of feelings of boredom and impatience. 8: Relaxation and breathing, prevention of relapse, maintaining stability

and ending the treatment.

Main outcome variables

Mood symptoms including mania and depression; the temptation to use substances

General information

Reason for update

Acronym

GCBT

IRCT registration information

IRCT registration number: **IRCT20170411033378N11**

Registration date: **2023-05-18, 1402/02/28**

Registration timing: **prospective**

Last update: **2023-05-18, 1402/02/28**

Update count: **0**

Registration date

2023-05-18, 1402/02/28

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2023-10-07, 1402/07/15 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty Scientific title The effect of group cognitive behavioral therapy on mood symptoms and temptation to substance use in male patients with bipolar disorder and substance dependence. Public title The effect of group cognitive behavioral therapy on mood symptoms and temptation to substance use. Purpose Education/Guidance Inclusion/Exclusion criteria Inclusion criteria: The diagnosis of bipolar disorder has been confirmed by a psychiatrist Have drug dependence Ability to communicate and answer questionnaires Being literate in reading and writing Consent to participate in the study Receive usual medical care and treatment Not having a physical or mental disability Not having another psychiatric disorder along with bipolar disorder Not participating in similar psychotherapy Exclusion criteria: Entering the acute phase of the disease Absence in more than 2 sessions of group therapy sessions Age From 18 years old to 65 years old Gender Male Phase N/A Groups that have been masked • Outcome assessor • Data analyser Sample size Target sample size: 40 Randomization (investigator's opinion) Randomized Randomization description The sampling method in this research is block randomization method. In this method, patients who meet the study entry criteria are divided equally and randomly into two intervention and control groups. For this purpose, blocks have been formed, within each block, half of the patients are placed in the intervention group and half of them are included in the control group. The main goal in this method is to balance the number of participants in each group. Considering that it is difficult to conduct group therapy for more than ten patients, and we have two intervention groups of ten, four blocks of ten are prepared. In each of these blocks, 5 patients are randomly placed in the intervention group (A) and 5 patients in the control group (B). The randomization sequence is provided through the following website:	https://www.sealedenvelope.com/simple-randomiser/v1/lits Blinding (investigator's opinion) Single blinded Blinding description Due to the clarity of the intervention received by the members of the groups involved in the study, it is practically impossible to blind the study participants. Therefore, in order to blind and prevent bias in all stages, completing the questionnaires and analyzing the data are done by people who do not know whether the patients are in the intervention group or the control group (People other than cognitive behavioral therapists). Placebo Not used Assignment Factorial Other design features Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Hamadan University of Medical Sciences Street address In front of Mardom Park, Hamedan University of Medical Sciences, City Hamadan Province Hamadan Postal code 38698 -65178 Approval date 2023-04-29, 1402/02/09 Ethics committee reference number IR.UMSHA.REC.1402.082 Health conditions studied <u>1</u> Description of health condition studied Bipolar disorder ICD-10 code F31.9 ICD-10 code description Bipolar affective disorder, unspecified <u>2</u> Description of health condition studied Substance dependence ICD-10 code F19.1
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ICD-10 code description

Mental and behavioural disorders due to multiple drug use and use of other psychoactive substances

Primary outcomes

1

Description

Mania score in Hirschfeld Mood Disorder Questionnaire (2000)

Timepoint

Measuring the mania score at the beginning of the study (before the start of the intervention), after the completion of the group cognitive behavioral therapy sessions, one month and three months after the completion of the sessions.

Method of measurement

Hirschfeld Mood Disorder Questionnaire (2000)

2

Description

Depression score in Beck Depression Questionnaire (short form with 13 questions)

Timepoint

Measuring the Depression score at the beginning of the study (before the start of the intervention), after the completion of the group cognitive behavioral therapy sessions, one month and three months after the completion of the sessions.

Method of measurement

Depression Questionnaire (short form with 13 questions)

3

Description

Temptation score in Wright's Craving Beliefs Questionnaire (2003)

Timepoint

Measuring the temptation score at the beginning of the study (before the start of the intervention), after the completion of the group cognitive behavioral therapy sessions, one month and three months after the completion of the sessions.

Method of measurement

Wright's Craving Beliefs Questionnaire (2003)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the intervention group includes 2 closed groups of 10 people (due to the limitation in the number of people present in the therapy group). For these people, in addition to the usual care, group cognitive behavioral therapy sessions are held for 8

sessions, two sessions a week, in the evenings in the classrooms in the psychiatry departments by a trained psychiatric nursing student and with the presence of the psychiatric nursing faculty experienced in this field. Each session will last 1.5 hours and about 10 minutes between sessions will be considered for rest and a short reception. Sessions are systematic with specific content and specific assignments for patients.

Category

Rehabilitation

2

Description

Control group: does not receive intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Educational and Medical Center

Full name of responsible person

Dr. Efat Sadeghian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan 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?**

No

Title of funding source

Hamadan 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**

Hamadan University of Medical Sciences

Full name of responsible person

Efat Sadeghian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

IPD briefly describe what specific participant data sets are to be shared
When the data will become available and for how long
Starting in Oct 2023
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used

People working in academic institutions
From where data/document is obtainable
Via Email: sadeghianefat@gmail.com
What processes are involved for a request to access data/document
Via Email: sadeghianefat@gmail.com
Comments