

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of the effectiveness of the Community Reentry Program (CRP) in adherence to treatment and control of symptoms of Bipolar Mood Disorder (BMD) in patients admitted to the psychiatric ward

Protocol summary

Study aim

Determining the effectiveness of CRP in bipolar type 1 patients admitted to male and female psychiatric wards.

Design

The type of study is an intervention with a control group. Receives an intervention group (CRP). And the control group does not receive any intervention. The intervention consists of 8-12 sessions, 4 sessions per week. Evaluation is done before and after the intervention and is followed up 3 months after discharge. Each person is evaluated for significant variables every two weeks and evaluated using the Yang Mania and SCL25 tests.

Settings and conduct

This study will be performed in the psychiatric ward of Fatemi Hospital in Ardabil.

Participants/Inclusion and exclusion criteria

The study population will be all patients with BMD disorder. A sample of bipolar type I patients admitted to the psychiatric ward of Dr. Fatemi Hospital in Ardabil. Took. A sample size of 50 will be selected and 25 people in each group will be included. Inclusion criteria: Having BMD disorder age 20-50 years, Exclusion criteria: mental retardation, schizophrenia, other psychotic disorders, duration less than 6 months, addiction.

Intervention groups

25 people in the intervention group will receive CRP interventions individually. The interventions will be presented individually in 8 to 12 sessions.

Main outcome variables

Adherence therapy aggression Mania symptoms
Community Relations

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211121053134N1**

Registration date: **2022-09-14, 1401/06/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-14, 1401/06/23**

Update count: **0**

Registration date

2022-09-14, 1401/06/23

Registrant information

Name

Mehriar Nadermohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of the Community Reentry Program (CRP) in adherence to treatment and

control of symptoms of Bipolar Mood Disorder (BMD) in patients admitted to the psychiatric ward

Public title

Evaluation of the effectiveness of the Community Reentry Program (CRP) in adherence to treatment and control of symptoms of Bipolar Mood Disorder (BMD).

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having BMD disorder Hospitalization in the psychiatric ward

Exclusion criteria:

Comorbidity with mental retardation Comorbidity with schizophrenia Comorbidity with other psychotic disorders Duration of the disorder less than 6 months Comorbidity with addiction

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be used. In this way, the patient randomly picks a card with two letters written on it. The letter I stands for intervention and the letter C stands for control. If a person takes a card that is I-C, that person will be placed in the intervention group, but the next person will be in the control group. If he takes the C-I card, that person will be placed in the control group and the next person will be placed in the intervention group. This action causes the number of groups to increase in parallel.

Blinding (investigator's opinion)

Single blinded

Blinding description

All patients in the intervention and control groups receive the intervention. But only the intervention group receives CRP. Individuals in the control group receive unrelated training. Neither patient in the two groups is informed of what the main intervention is.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Address: Ardabil, Daneshgah st. Ardabil Complex Univesity

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Province

Ardabil

Postal code

56189-85991

Approval date

2021-11-16, 1400/08/25

Ethics committee reference number

IR.ARUMS.REC.1400.244

Health conditions studied

1

Description of health condition studied

Bipolar Mood Disorder (BMD-I)

ICD-10 code

296/41

ICD-10 code description

296/41

Primary outcomes

1

Description

Signs and symptoms of bipolar disorder, drug adherence, aggression, and social relationships are outcome variables that are assessed with the following questionnaires. 1- Young Mania 2- Morisky Drug Adherence Questionnaire 3- Phillips Social Support Questionnaire 4- Bass Perry Aggression Questionnaire.

Timepoint

Before each intervention session (8 to 12 sessions) and after discharge from the ward (up to 2 months each week)

Method of measurement

Use a self-report questionnaire: 1- Young Mania 2- Morisky Drug Adherence Questionnaire 3- Phillips Social Support Questionnaire 4- Bass Perry Aggression Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

The Community Reenter Program (CRP) is a subset of the more comprehensive program, The Independent and Social Life Skills Program, developed by the Psychiatric Rehabilitation Clinical Research Center at UCLA, for people with long-term and recurrent mental disorders, especially schizophrenia. "Bipolar disorder and major depression are designed. The purpose of the Return to Community program is to provide patients with the information and skills necessary for an independent social life and to enable them to benefit from psychosocial rehabilitation services." The Return to Community program combines new educational materials in discharge planning and application in the community with areas of drug treatment management, symptom self-management, and leisure and recreation programs. Is used.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi Hospital - Psychiatric Department

Full name of responsible person

Dr. Fariba Sadeghi Movahed

Street address

Ardabil - Sarein Station; Imam Khomeini St., not far from Shariati Square, Fatemi Educational and Medical Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Farhad Pourfarzi

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Ardabil: The end of Daneshgah Street, the administrative complex of Ardabil University of

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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

50

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

مهربار ندر محمدی

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

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

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

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

The overall results will be published in the article that will be published

When the data will become available and for how long

Unlimited

To whom data/document is available

All

Under which criteria data/document could be used

To design similar studies or launch CRP services

From where data/document is obtainable

Related scientific journals

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

Written request to the responsible author specifying the scientific and clinical status

Comments

not