Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of family Psychoeducational Intervention on the Burden and perceived stress of Caregivers of Patients with Bipolar Disorder

Protocol summary

Study aim

Determining the effectiveness of family psychoeducation intervention on the psychological burden and perceived stress of caregivers of patients with bipolar disorder

Design

The clinical trial has a control group and is randomized and nonblinded on 72 people. The block randomization method generated by Random Allocation Software was used for randomization.

Settings and conduct

The level of psychological burden and perceived stress will be assessed by the research members using the Zarit Psychological Burden Questionnaire and the Perceived Stress Questionnaire. Then, the intervention group will undergo psychological education sessions on bipolar disorder. The educational sessions will be held at Shahid Yahyanejad Hospital. Then, the aforementioned questionnaires will be completed again by the control and intervention groups after the end of the intervention and three months after the end of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria for caregivers: Age 18-60 years At least fifth grade education Individuals from the patient's first-degree family who are consistently responsible for caring for him/her Caregivers whose patients have had at least two mood episodes during the course of the disease Criteria for excluding caregivers from the study: People who have a history of psychiatric disorder or physical illness that affects their role in caring for the patient People who have a history of participating in similar training sessions or are currently participating in other similar training sessions at the time of the study.

Intervention groups

For individuals in the study group, education on bipolar disorder will be provided by the resident responsible for implementing the project during four forty-five-minute sessions held over two weeks.

Main outcome variables

Psychological burden؛ perceived stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250609066133N1**
Registration date: **2025-07-10, 1404/04/19**
Registration timing: **prospective**

Last update: **2025-07-10, 1404/04/19**
Update count: **0**

Registration date

2025-07-10, 1404/04/19

Registrant information

Name
Maryam Haghjou
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 3222 3594
Email address
haghjou29@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-16, 1404/04/25

Expected recruitment end date

2025-10-22, 1404/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of family Psychoeducational Intervention on the Burden and perceived stress of Caregivers of Patients with Bipolar Disorder

Public title
The Effectiveness of family Psychoeducational Intervention on the Burden and perceived stress of Caregivers of Patients with Bipolar Disorder
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age from 18 to 60 At least fifth grade education People from the patient's immediate family who are permanently responsible for his or her care Caregivers whose patients have had at least two mood episodes during the course of their illness
Exclusion criteria:
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be used to assign target group patients to one of the two study groups. Then, participants will be assigned to one of the two intervention and control groups in blocks of six in a 1:1 ratio according to the block randomization protocol (generated by Random Allocation Software), so that the researcher cannot predict which intervention group the next person will be placed in. In order to conceal the random allocation, the codes generated by the software will be placed in opaque envelopes so that it is not clear which group the next person will be placed in.
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
Research Ethics Committees of Health Research Institute - Babol University of Medical Sciences
Street address
Babol University of Medical Sciences , Ganafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
4717647745
Approval date
2025-05-18, 1404/02/28
Ethics committee reference number
IR.MUBABOL.HRI.REC.1404.024

Health conditions studied

1

Description of health condition studied
Bipolar disorder
ICD-10 code
F31
ICD-10 code description
Bipolar disorder

Primary outcomes

1

Description
Psychological burden score on the Zarit Psychological Burden Questionnaire
Timepoint
Measurement of psychological burden before the start of the intervention, after the intervention, and three months after its end
Method of measurement
Zarit burden interview

2

Description
Perceived stress score on the Perceived Stress Test
Timepoint
Measurement of perceived stress at the beginning of the study, after the intervention, and three months after the intervention
Method of measurement
Perceived Stress Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Individuals in this group will receive training on bipolar disorder in four 45-minute sessions

over two weeks, two sessions each week. The content will be taught by the resident implementing the project. The source of the information taught will be Kaplan and Sadock's Comprehensive Psychiatry, 11th edition, and the book Treatment of Bipolar Disorder: Cognitive Behavioral Approach.

Category

Prevention

2

Description

Control group: The control group will not undergo psychological training as will be done for the intervention group. The level of care in this group will be the same as usual.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahyanejad hospital

Full name of responsible person

Maryam Haghjou

Street address

Shahid Mostafa Khomeini Ave.,Modarres Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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Vice_chanceller Of Research., Daneshgah Square., Ganjafrooz Avenue

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Maryam Haghjou

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Modarres Street,Shahid Yahyanejad Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The participant data file will be published without publishing the names of the individuals, the study protocol, the statistical analysis map, the informed consent form, the clinical study report, the codes used in the analysis, and the data classification system after the end of the study.

When the data will become available and for how long
Start of access period since 2025

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Permitted analyses include descriptive and inferential statistical analyses. Data may only be used for research and scientific purposes, including publication of articles and reports. Commercial use of the data is not permitted.

From where data/document is obtainable
To receive the data, they can send their request to the email of the student responsible for the research, Maryam Haghjou .Adress:haghjou29@gmail.com

What processes are involved for a request to access data/document
The applicant must submit a formal request including the purpose and type of data. The request is sent to the review committee and usually takes 1 to 2 weeks to evaluate. The applicant is notified after the request is approved or rejected. If approved, a privacy agreement must be signed. The data is sent to the applicant after the agreement is signed, which may take 1 to 3 weeks.

Comments