Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the efficacy of group psychoeducation through in_person meeting, on the symptoms and functional recovery of patients with bipolar disorder

Protocol summary

Study aim

Evaluation of the efficacy of group psychoeducation through in_person meeting, on the symptoms and functional recovery of patients with bipolar disorder.

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, phase 2 on 34 patients. NCSS (Number Cruncher statistical system) software and block random method are used to randomize the study

Settings and conduct

34 patients with schizophrenia who referred to Ibn Sina Psychiatric Hospital in Shiraz in 2020-21will be included in the study. These people will then be randomly divided into groups receiving intervention and placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having bipolar disorder type 1or 2; tHave been in the remission phase for at least three months. Exclusion criteria: having concomitant psychiatric illness; Substance use; Intellectual disability; Simultaneous neurological disease

Intervention groups

Intervention group: In this group, face-to-face training sessions are held based on the Barcelona psychological training model (which includes 21 training sessions and the shortened course is 10 sessions). The number of members in each group will be between six and nine. Meetings will be held twice a week for 45-60 minutes at Ibn Sina Educational and Medical Center in Shiraz.
Control group: In the control group, ten training sessions with the same structure described for the intervention group (Meetings twice a week for 45-60 minutes) in the field of prevention and public health for individuals.

Main outcome variables

Change in The 36-Item Short Form Survey (SF-36)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190726044339N2**
Registration date: **2020-12-12, 1399/09/22**
Registration timing: **prospective**

Last update: **2020-12-12, 1399/09/22**
Update count: **0**

Registration date

2020-12-12, 1399/09/22

Registrant information

Name

Seyed Hamdollah Mosavat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 4105

Email address

hamdi_88114@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-20, 1399/09/30

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the efficacy of group psychoeducation through in_person meeting, on the symptoms and functional recovery of patients with bipolar disorder

Public title
Evaluation of the efficacy of group psychoeducation on the symptoms and functional recovery of patients with bipolar disorder

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Having bipolar disorder type 1or 2 Have been in the remission phase for at least three months Age range 18-50 years

Exclusion criteria:
Having other psychiatric disorder Substance use Intellectual disability Simultaneous neurological disease

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
The researcher will enrolled participants based on convenience sampling method. NCSS software (Number Cruncher Statistical System) and block randomization method will use for randomization the study. In the block randomization method, participants will categorize into 6 blocks (AABB, ABAB, BBAA, BABA, ABBA, BAAB), each block containing 4 participants. In this study, "A" will assign to the drug group and "B" to the placebo group, for example: in the "ABAB" block, the first person entered the drug group, the second person entered the placebo group, the third person entered the drug group, and the fourth person entered the placebo group. Thus, all eligible participants will randomly assigned to one of the study arms according to the randomization list.

Blinding (investigator's opinion)
Single blinded

Blinding description
The person who fills out the questionnaire and the person who teaches are two separate people. Therefore, the educator is not blind to the participants, but the person who records the consequences is blind to the study groups. Participants also do not know whether they are part of the intervention group or the control group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Ibn Sina Hospital; Hafez street

City
Shiraz

Province
Fars

Postal code
7134845794

Approval date
2020-04-06, 1399/01/18

Ethics committee reference number
IR.SUMS.MED.REC.1399.024

Health conditions studied

1

Description of health condition studied
Bipolar disorder, currently in remission

ICD-10 code
F31.7

ICD-10 code description
Bipolar disorder, currently in remission

Primary outcomes

1

Description
Change in The 36-Item Short Form Health Survey (SF-36) score

Timepoint
Six months

Method of measurement
The 36-Item Short Form Health Survey (SF-36)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, face-to-face training sessions are held based on the Barcelona psychological training model (which includes 21 training sessions and

the shortened course is 10 sessions). The number of members in each group will be between six and nine. Meetings will be held twice a week for 45-60 minutes at Ibn Sina Educational and Medical Center in Shiraz.

Category

Treatment - Other

2

Description

Control group: In the control group, ten training sessions with the same structure described for the intervention group (Meetings twice a week for 45-60 minutes) in the field of prevention and public health for individuals

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

bn Sina Psychiatric Hospital(Shiraz

Full name of responsible person

Amir Bazrafshan

Street address

Hafez street

City

Shiraz

Province

Fars

Postal code

71466 76549

Phone

+98 71 3228 9604

Email

bazrafshana@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Amir Bazrafshan

Street address

Hafez street

City

Shiraz

Province

Fars

Postal code

71466 76549

Phone

+98 71 3228 9604

Email

bazrafshana@sums.ac.ir

Grant name

Vice Chancellor for Research, Shiraz University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Narjes Saburian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Ibn Sina Hospital, Hafez St.

City

Shiraz

Province

Fars

Postal code

7654971466

Phone

+98 71 3228 9601

Email

hamdi_88114@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Hamdollah Mosavat

Position

Resident

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

Street address

Ibn Sina Hospital, Hafez St.

City

Shiraz

Province
Fars

Postal code
7654971466

Phone
+98 917 840 1495

Email
hamdi_88114@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Seyed Hamdollah Mosavat

Position
Resident

Latest degree
Ph.D.

Other areas of specialty/work
Psychiatrics

Street address
Ibn Sina Hospital, Hafez St.

City
Shiraz

Province
Fars

Postal code
7654971466

Phone
+98 917 840 1495

Email
hamdi_88114@yahoo.com

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

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

Informed Consent Form
Undecided - It is not yet known if there will be 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