

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A Clinical Trial to assess the Effectiveness of Family-Based Interventions on Severity of Symptoms, Stigma, Caregiver Burden, Emotion Expression and Coping Styles among Family Members of Bipolar Patients.

Protocol summary

Summary

This research is an experimental research. It evaluates the effectiveness of family-based Interventions on family members of Bipolar Patients. The research aims to deliver a therapeutic guideline based on Iranian culture. Sixty subjects from family members and caregivers of patients with bipolar spectrum disorders are randomly selected. Their diagnosis has been confirmed by psychiatrist. Family member has no considerable mental disorder, has at least primary school education, and is in age range of 25-60 years old. For randomization, all patients who met inclusion criteria are selected and a code is specified to each patient. By randomly drawing, patients will be allocated to intervention and control groups and will participate in group therapy sessions after filling the written consent form. Group therapy sessions will be applied to one of the family members who has the most contact with patient, in 12 sessions within 4 weeks and is based on Micklowitz package adapted for Iranian culture. Young Mania Rating Scale (YMRS), Zarit Caregivers Burden Inventory, Stigma, Emotion Expression Questionnaire (EEQ) and Coping Inventory for Stressful Situations (CISS) will be completed by family members before, at the end and after 3 months of therapy sessions termination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061434533N1**
Registration date: **2017-09-25, 1396/07/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-25, 1396/07/03

Registrant information

Name

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Name of organization / entity

University of Social Welfare and Rehabilitation Sciences.

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical Trial to assess the Effectiveness of Family-Based Interventions on Severity of Symptoms, Stigma, Caregiver Burden, Emotion Expression and Coping Styles among Family Members of Bipolar Patients.

Public title

Effectiveness of Family-Based Interventions on Family

Members of Bipolar Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of Bipolar Disorder based on DSM-IV-TR (American Psychiatric Association, 2000) and psychiatrists' diagnostic interview; the Bipolar Disorder diagnosis should be confirmed by SCID (Structured clinical interview); The age range of 25 to 60 years old; Family member should be educated at least 8 grades; Patient should live with the family member before and after hospitalization; The family member should be psychological minded and should have enough eager and ability to understand therapeutic constructs. Exclusion criteria: The group participant has considerable mental disorder diagnosis that report in axis I in DSM-IV-TR diagnostic classification.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

For randomization all patients who met inclusion and exclusion criteria will select and we specify a code to each patient. Through drawing randomly by a blind person to purpose of study, patients allocate to intervention and control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation Sciences

Street address

University of Social Welfare and Rehabilitation Sciences, Kodakryar st., Daneshjoo Blv, Velenjak.

City

Tehran

Postal code

Approval date

2016-10-01, 1395/07/10

Ethics committee reference number

IR.USWR.REC.1395.166

Health conditions studied

1

Description of health condition studied

Bipolar Disorder

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorder

Primary outcomes

1

Description

caregiver burden

Timepoint

before intervention, after intervention, 3months follow-up

Method of measurement

Zarit Caregiver Burden Inventory

2

Description

stigma

Timepoint

before intervention, after intervention, 3months follow-up

Method of measurement

Michel King Stigma Inventory

3

Description

coping styles

Timepoint

before intervention, after intervention, 3months follow-up

Method of measurement

CISS- Coping Inventory in stressful Situations

4

Description

emotion expression

Timepoint

before intervention, after intervention, 3months follow-up

Method of measurement

Emotional Expressiveness Questionnaire EEQ

5

Description

bipolar disorder symptoms

Timepoint

before intervention, after intervention, 3months follow-up

Method of measurement

YMRS Young mania rating scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group: Family members will receive family-based psychotherapy within 3 10-member groups. Family based psychotherapy consists of 12 session. The duration of each session is 90 minutes. The sessions contain these topics: knowledge about the disease, bio-psycho-social model, symptoms of bipolarity, mood stabilizer medications, medication compliance, knowledge about mood swings, how to apply mood graphs, relation between mood and situations, family members as predisposing events, reviewing the level of activity, regulating restrictions before reaching problematic level, crisis management and problem solving, family members tension reduction practices and relapse prevention.

Category

Behavior

2**Description**

Control Group: It consist of family members of patients with bipolar spectrum disorders. They will not receive intervention. They only complete questionnaires on pretest, post test and follow-up.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razi Psychiatric Hospital

Full name of responsible person

Dr Mohammad Sayad Nasiri

Street address

Psychosis Research Center, Chahardehi Building, Razi Psychiatry Center, Amin Abad, Shahr- Rey.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research of Social Welfare and Rehabilitation Sciences University.

Full name of responsible person

Dr. Yadegari, Fariba.

Street address

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City

Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for Research of Social Welfare and Rehabilitation Sciences University.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Psychosis Research Center

Full name of responsible person

Neda Ali Beigi

Position

Assistant Professor, Ph.D in Clinical Psychology

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data**Contact****Name of organization / entity**

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Sciences

Full name of responsible person

Neda Ali Beigi

Position

Ph.D/ Assistant Professor

Other areas of specialty/work