

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effect of psycho-education program on internalized stigma in clients with bipolar disorder

Protocol summary

Summary

-Aim of study: Effect of psycho-education on internalized stigma of clients with bipolar disorder. -Method of study: This is a Non-randomized controlled clinical trial. Inclusion criteria: suffering from bipolar disorder type one or two according to medical records; participants aged 18 to 60 years. Exclusion criteria: Suffering from cognitive disorder such as Alzheimer's. This study will be carried out among 84 patients with bipolar disorder type one or two. Equal number of volunteers from both gender will be entered to the trial. Method: Participants of this study are patients with bipolar disorder who are hospitalized in Iran Psychiatry Hospital. Participants will be selected based on inclusion criteria. Psycho-educational program for client will be held in group of 5 to 8 members, during six session 60 minute (three times a week). The control group will be received only routine interventions. The inventory for Internalized Stigma of Mental Illness (ISMI) will be used in this study. the questionnaire will be completed by both groups before the start of intervention (pre-test) and three weeks after start of intervention (post-test). The time required for full implementation is 12 months. Project outcomes: Internalized stigma of client with bipolar disorder.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060923683N3**
Registration date: **2017-02-10, 1395/11/22**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Naiemeh Seyedfatemi

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, School of Nursing and Midwifery

Expected recruitment start date

2016-09-18, 1395/06/28

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of psycho-education program on internalized stigma in clients with bipolar disorder

Public title

Effect of psycho-education on stigma in clients with bipolar disorder

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: suffering from bipolar disorder type one or two according to medical records; being hospitalized for at least one week; participants aged 18

to 60 years; the ability to participate in the group;
Exclusion criteria: Suffering from cognitive disorder such as Alzheimer's.

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: **84**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences Ethics Committee

Street address

Hemmat Highway, Tehran

City

Tehran

Postal code

Approval date

2016-06-06, 1395/03/17

Ethics committee reference number

IR.IUMS.REC. 1395.9311688006

Health conditions studied

1

Description of health condition studied

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorder

2

Description of health condition studied

Bipolar disorder

ICD-10 code

F30

ICD-10 code description

Manic episode

Primary outcomes

1

Description

Internalized Stigma

Timepoint

Before and three weeks after intervention

Method of measurement

Internalized Stigma of Mental Illness (ISMI) scale

Secondary outcomes

empty

Intervention groups

1

Description

Psycho-educational program for client will be held in group of 5 to 8 members during six session 60 minute, three times a week. Each session will be started with a summary of the previous session, and the main topic will be thought, at the end of the each session the main points will be reviewed and clients' questions will be answered.

Category

Other

2

Description

The control group will be received only ward routine interventions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Psychiatric Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences, School of Nursing and Midwifery

Full name of responsible person

Nahid Akbari

Street address

School of Nursing and Midwifery-Rasheed Yassami
Street-Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences, School of Nursing
and Midwifery

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**

Iran University of Medical Sciences, School of Nursing
and Midwifery

Full name of responsible person

Zinat Keshavarz

Position

Masters student

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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