

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of psycho-educational group therapy on internalized stigma of family caregivers of children with Bipolar mood disorder

Protocol summary

Summary

(1) Objectives: The aim of this study is to examine the effect of psycho-educational group therapy on internalized stigma of family caregivers of children with Bipolar mood disorder. (2) Design: This research is an experimental study with a "pre-test, post-test and follow-up with control group" design. (3) Setting and conduct: The sample size of this study estimated 88 persons that randomly 44 persons in control group and 44 persons in experimental group will allocated. Instruments for data gathering are Demographic Questionnaire and Modified Version of Internalized Stigma Questionnaire. (4) Participants will be chosen based on inclusion and exclusion criteria. (5) Interventions: Firstly the pre-test will be done in both groups. The experimental group will attend eight sessions of 90 minutes in psycho-educational group therapy. The control group will not receive any intervention in this duration. Then the post-test and follow up after one month will be done on both group. Finally the results of the two groups will be compared. (6) The main outcome variable: Reducing internalized stigma in receiving psycho-educational group therapy

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605026834N10**

Registration date: **2016-12-17, 1395/09/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-17, 1395/09/27

Registrant information

Name

Hossein Ebrahimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research Vice- Chancellor, Tabriz University of Medical Sciences

Expected recruitment start date

2016-08-01, 1395/05/11

Expected recruitment end date

2017-02-01, 1395/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of psycho-educational group therapy on internalized stigma of family caregivers of children with Bipolar mood disorder

Public title

The effect of group therapy on stigma of family of children with Bipolar mood disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Family caregiver who has not major Psychiatry problem; is first-degree relative with the patient; is the primary carer of the patient; lives in a

house with the patient; has at least ability to write and read; is at least 18 and up to 60 years old; and has obtained a minimum score of 42.5 in the stigma questionnaire in pretest; the diagnosis of his/her child is confirmed by a psychiatrist based on DSM V standards; his/her child is treated as outpatient; and his child is at least 8 and up to 18 years old. Exclusion criteria: Family caregiver has to decide to participate in other training program; dose not want to continue to participate in the study; experiences acute crisis such as divorce and death of loved one during the study; has history of substance abuse (according to self-reported); is graduated in the fields of medical sciences; has a history of serious physical illness, and known mental disorder; has absence more than one session from training sessions; his/her child hospitalized during the study; and his/her child has alcohol and drug dependency (according to the doctor or primary caregiver report).

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences, Research Vice- Chancellor

Street address

Third floor, Central Building- No 2, Golgasht Street

City

Tabriz

Postal code**Approval date**

2016-06-13, 1395/03/24

Ethics committee reference number

IR.TBZMED.REC.1395.268

Health conditions studied**1****Description of health condition studied**

Bipolar affective disorder

ICD-10 code

F31.7

ICD-10 code description

bipolar affective disorder, currentlly in remission

Primary outcomes**1****Description**

Internalized Stigmatization

Timepoint

Before, afer and one months after the intervention

Method of measurement

Internalized Stigmatization Scale of Mental Illnesses(ISSMI) Questionnaire

Secondary outcomes

empty

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

Intervention group: Firstly, the pre-test will be done. Intervention group will receive 8 sessions therapy by the researcher. Then, the post-test and follow up will be done. Finally, the differences of pre-test, post-test and follow-up are compared with each other.

Category

Prevention

2**Description**

Control group: This group will not receive any intervention. The differences of pre-test and post-test and follow up are measured and are compared with each other.

Category

Prevention

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

Razi Psychiatric Hospital

Full name of responsible person

Dr Arash Mohaggegi

Street address

Tabriz Razi Psychiatric Hospital, Elgoli Boulevard East Azarbayjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice- Chancellor, Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Rashidi

Street address

Third floor, No 2 Building of Tabriz University of Medical Sciences, Golgasht Ave Tabriz

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice- Chancellor, Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Somaye Janmohammadi

Position

MS in Psychiatric Nursing, Student

Other areas of specialty/work

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Other areas of specialty/work

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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