

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Family-centered Psychoeducation on Mental Health and Quality of life of Families of Adolescents with Bipolar disorder referred to Medical centers Affiliated to Shiraz University of Medical Sciences.

Protocol summary

Summary

This study aimed to evaluate the effect of family-base Psycho-educational on mental health and quality of life of families with bipolar adolescents(12-18 years old) referring hospital affiliated to Shiraz University of Medical Sciences in 2012.This study included 40 family that have bipolar adolescents. Inclusion criteria: no mental illness(according to self-report forms); persons participating in the study have the willing to participate in research; family have adolescents aged 12-18 years old with BD; parents have the lowest literacy through fifth grade; adolescent have not mental retardation, seizure disorder, substance abuse and schizophrenia; have signed a written informed consent. Exclusion criteria: unwillingness to participate in the study; lack of coordination of research; failure to participate in more than 2 sessions.The experimental group participated in 6 sessions of Psycho- educational intervention.The control group did not receive any intervention.At the end of the intervention to ethics the control group received an educational pamphelat and this group participated in two sessions.Before,immediately and one month after intervention,Public Health and Quality of life of two groups was measured by General Health Questionnaire and SF36.

General information

Acronym

psycho-educational intervention

IRCT registration information

IRCT registration number: **IRCT201304202812N15**

Registration date: **2015-07-15, 1394/04/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-15, 1394/04/24

Registrant information

Name

Farkhondeh Sharif

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1212 2401

Email address

fsharif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-01-10, 1392/10/20

Expected recruitment end date

2014-04-04, 1393/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Family-centered Psychoeducation on Mental Health and Quality of life of Families of Adolescents with Bipolar disorder referred to Medical centers Affiliated to Shiraz University of Medical Sciences.

Public title

Effect of education on family with bipolar adolescent

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: no mental illness(according to self-report forms); persons participating in the study have the willing to participate in research; family have adolescents aged 12-18 years old with BD; parents have the lowest literacy through fifth grade; adolescent have not mental retardation, seizure disorder, substance abuse and schizophernia; have signed a written informed consent. Exclusion criteria: unwillingness to participate in the study; lack of coordination of research; failure to participate in more than 2 sessions.

Age
From **12 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

1

Registry name
مرکز ثبت کارآزمایی بالینی

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Science

Street address
Shiraz,Zand street,University of Medical Science Building

City
Shiraz

Postal code

Approval date
2013-10-06, 1392/07/14

Ethics committee reference number

CT-92-6718

Health conditions studied

1

Description of health condition studied
Bipolar disorder

ICD-10 code
F31.9

ICD-10 code description

Primary outcomes

1

Description
General Health.

Timepoint
Before, immediately, one month after intervention

Method of measurement
General Health questiopnnnaire(GHQ28)

Secondary outcomes

1

Description
Quality of life

Timepoint
Before, immediately and one month after intervention

Method of measurement
SF36

Intervention groups

1

Description
Psycho-educational intervention for families in experimental group in 6 sessions .

Category
Prevention

2

Description
The Control group did not receive any intervention.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hafez Hospital

Full name of responsible person
Dr Farkhonde Sharif

Street address

City
Shiraz

2

Recruitment center

Name of recruitment center
Ebne sina Hospital
Full name of responsible person
Dr Farkhonde Sharif
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
shiraz university of medical science
Full name of responsible person
Dr Gholamreza Hatam
Street address
Shiraz university of medical sciences,university
central building,Beside Red cross,Zand street
City
Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

shiraz university of medical science

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
Shiraz University of Medical Sciences
Full name of responsible person
Dr Farkhondeh Sharif
Position
Professor
Other areas of specialty/work
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**Person responsible for scientific
inquiries**

Contact

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Person responsible for updating data

Contact

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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