

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Study of the effect of family Psycho-education of bipolar patients on family expressed emotion and relapse

#### Protocol summary

Expressed emotion; The rate of disease relapses

#### Study aim

The effect of family Psycho-education of bipolar patients on family expressed emotion and relapse

#### Design

Study is done as clinical trial on the family with patients who diagnosed to bipolar disorder and hospitalized in 22 Bahman hospital of Qazvin, in the recent 6 months.

#### Settings and conduct

The aim of this study is evaluating the effect of psychological education of families of patients with bipolar disorder on families' emotional expression and disease relapse. Study is done as clinical trial on family with patients and hospitalized in 22 Bahman hospital of Qazvin, in the recent 6 months. Inclusion criteria are an age range from 20 to 60 years old and patients in the same condition of disease. In the case of dissatisfaction, Family is excluded of the study. Families are attended to a general session to justify the outline of method and to fill questionnaire. They are educated weekly through an educational set for two sessions in 2 hours. The educational sessions are present by psychologist researcher in a conference room at the hospital. After 6 months, families are invited to fill the questionnaire, and disease relapse is assessed by psychologist researcher by interview.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: A member of family with bipolar disorder diagnosed by psychologist, trusty patients' caregiver, family or caregiver without disease symptoms history, family with hospitalized patients in a recent 6 months in center, patients in the same condition of disease severity and in age range from 20 to 60 years old. Exclusion criteria: contributed caregivers with psychiatric disease, and family with dissatisfaction

#### Intervention groups

Intervention group: Family of patients with bipolar disorder Type of intervention: Weekly training using an educational set in two sessions for 2 hours

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180223038835N2**

Registration date: **2018-04-07, 1397/01/18**

Registration timing: **retrospective**

Last update: **2018-04-07, 1397/01/18**

Update count: **0**

##### Registration date

2018-04-07, 1397/01/18

##### Registrant information

###### Name

Zahra Hashemi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3355 5978

###### Email address

z.hashemi@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-27, 1396/07/05

##### Expected recruitment end date

2018-03-25, 1397/01/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Study of the effect of family Psycho-education of bipolar patients on family expressed emotion and relapse

### Public title

The effect of family Psycho-education of bipolar patients and relapse

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

A member of family with bipolar disorder diagnosed by psychologist  
Trusty patients' caregiver  
Family or caregiver without disease symptoms history  
Family with hospitalized patients in a recent 6 months in center  
Patients in the same condition of disease severity  
Age range from 20 to 60 years old

#### Exclusion criteria:

Contributed caregivers with psychiatric disease  
Family with dissatisfaction

### Age

From **20 years** old to **60 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **36**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

##### Street address

Shahid Bahonar Blvd.

##### City

Qazvin

##### Province

Qazvin

### Postal code

34139-96134

### Approval date

2017-09-24, 1396/07/02

### Ethics committee reference number

IR.QUMS.REC1396.273

## Health conditions studied

### 1

#### Description of health condition studied

Bipolar disorder

#### ICD-10 code

F31

#### ICD-10 code description

Bipolar disorder

## Primary outcomes

### 1

#### Description

Expressed emotion

#### Timepoint

Before and 6 months after intervention

#### Method of measurement

Family Questionnaire (FQ)

## Secondary outcomes

### 1

#### Description

The Rate of disease relapses

#### Timepoint

Before and 6 months after intervention

#### Method of measurement

Interview

## Intervention groups

### 1

#### Description

Intervention group: Family of patients with bipolar disorder

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

22 Bahman hospital of Qazvin

##### Full name of responsible person

Dr Seyede Zahra hashemi

##### Street address

22 Bahman Hospital, Rah'ahan street, Qazvin.

**City**  
Qazvin  
**Province**  
Qazvin  
**Postal code**  
34139-96134  
**Phone**  
+98 28 3333 5800  
**Email**  
dr.zahra.hashemi.78@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Dr Amir Peymani  
**Street address**  
Vice chancellor for research, Qazvin University of  
Medical Sciences, Valiasr street, Qazvin  
**City**  
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#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Qazvin 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**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Dr Seyede Zahra Hashemi  
**Position**  
Specialist  
**Latest degree**

Ph.D.

#### Other areas of specialty/work

Psychiatrics

#### Street address

22 Bahman Hospital, Rah'ahan street, Qazvin

#### City

Qazvin

#### Province

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#### Postal code

34139-96134

#### Phone

+98 28 3333 5800

#### Email

dr.zahra.hashemi.78@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Dr Seyed Mohsen Zamir  
**Position**  
Associate  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
22 Bahman Hospital, Rah'ahan street, Qazvin  
**City**  
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**Province**  
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dr.zahra.hashemi.78@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Dr Seyede Zahra Hashemi  
**Position**  
Specialist  
**Latest degree**  
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**Postal code**

34139-96134

**Phone**

+98 28 3333 5800

**Email**

dr.zahra.hashemi.78@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

According to contents of consent form

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available