Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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
Expressed emotion; The rate of disease relapses

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
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Iran (Islamic Republic of)
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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.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr Amir Peymani
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Vice chancellor for research, Qazvin University of Medical Sciences, Valiasr street, Qazvin
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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
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Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

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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