

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparing the effect of continuous care model and supportive psychoeducation package on self-care in patients with bipolar disorder type 1

#### Protocol summary

##### Summary

Objectives: Comparing the effect of continuous care model and supportive psychoeducation package on self-care in patients with bipolar disorder type 1. Design: this study was performed on 90 patients with type 1 bipolar disorder (which is in the process of stabilization) by available sampling method. Then, they will be assigned randomly according to the random numbers table into three groups: continuous care model, supportive psychoeducation package and control. Methodology: in the continuous care model, patients will be trained in four stages of awareness (a two-hour session), sensitization (6 sessions per 2 hours), control (once every two weeks), and evaluation (at each stage) For 12 weeks. In supportive psychoeducation package group, patients will receive standard training package in the form of a booklet and CD during a one-hour session after discussing on bipolar disorder. The control group will receive the usual training. Major eligibility criteria for participants: at least high school level, lack of mental retardation, confirmation of bipolar disorder by psychiatrist, not having chronic physical illness simultaneously, not having cognitive impairment simultaneously, living with the caregiver. Major criteria for no eligibility: unwillingness to continue participating in the study, Missing more than one session at training sessions, having a degree in medicine, nursing, psychology

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2017071735141N1**

Registration date: **2017-08-26, 1396/06/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-08-26, 1396/06/04

##### Registrant information

###### Name

Azam Mohammady

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3459 1375

###### Email address

mohammadya1@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for research of Mashhad University of Medical Sciences

##### Expected recruitment start date

2017-07-06, 1396/04/15

##### Expected recruitment end date

2017-10-07, 1396/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of continuous care model and supportive psychoeducation package on self-care in patients with bipolar disorder type 1

##### Public title

Comparing the effect of continuous care model and psychoeducation package on self-care

### **Purpose**

Supportive

### **Inclusion/Exclusion criteria**

Major eligibility criteria for participants: at least high school level; lack of mental retardation; confirmation of bipolar disorder by psychiatrist; not having chronic physical illness simultaneously; not having cognitive impairment simultaneously; living with the caregiver. Exclusion criteria: unwillingness to continue participating in the study; Missing more than one session at training sessions; having a degree in medicine, nursing, psychology

### **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: **90**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

Patients with type 1 bipolar disorder were selected according to the physician's approval at the mood stabilization stage

## **Secondary Ids**

### 1

#### **Registry name**

-

#### **Secondary trial Id**

-

#### **Registration date**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Mashhad university of medical sciences

##### **Street address**

Vice chancellor for research, Mashhad University of Medical Sciences, next to the Hovezeh Cinema,

University avenue, Mashhad

#### **City**

Mashhad

#### **Postal code**

00985138430249

#### **Approval date**

2010-09-23, 1389/07/01

#### **Ethics committee reference number**

IR.MUMS.REC.1396.119

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Bipolar Disorder type 1

#### **ICD-10 code**

F31

#### **ICD-10 code description**

Bipolar affective disorder

## **Primary outcomes**

### 1

#### **Description**

self- care

#### **Timepoint**

before intervention, two months after intervention

#### **Method of measurement**

Roldán-Merino self-care needs questionnaire

### 2

#### **Description**

self- efficacy

#### **Timepoint**

before intervention, two months after intervention

#### **Method of measurement**

Lorig chronic disease self-efficacy scales

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

The control group will receive the usual training

#### **Category**

Other

### 2

#### **Description**

Continuous care mode group: patients will be trained in four stages of awareness (a two-hour session), sensitization (6 sessions per 2 hours), control (once every two weeks), and evaluation (at each stage) For 12 weeks

**Category**

Other

**3****Description**

Supportive psychoeducation package group: patients will receive a standard training package in the form of a booklet and CD during a one-hour session after discussing on bipolar disorder

**Category**

Other

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

Ibn Sina psychiatric hospital, Mashhad

**Full name of responsible person**

Dr Fateme Mohareri

**Street address**

Next Astan Ghods Naghlie, end Hor Ameli of the street, Mashhad

**City**

Mashhad

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Vice chancellor for research, Mashhad University of Medical Sciences, next to the Hovezeh cinema, Daneshgah avenue, Mashhad

**City**

Mashhad

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

Yes

**Title of funding source**

Vice Chancellor for research of Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Azam Mohammady

**Position**

Msc in psychiatric nursing

**Other areas of specialty/work****Street address**

Mashhad University of Medical Sciences, next to the Hovezeh cinema, Daneshgah avenue, Mashhad

**City**

Mashhad

**Postal code****Phone**

+98 51 3843 0249

**Fax****Email**

Mohammadya1@mums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Azam Mohammady

**Position**

Msc in psychiatric nursing

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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+98 51 3843 0249

**Fax****Email**

mohammadya1@mums.ac.ir

**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*