

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Investigating the Impact of Problem-Solving Skills Training on the Aggression Severity in Patients with Type 1 Bipolar Disorders

#### Protocol summary

##### Summary

The purpose of this study was to investigate the effect of problem solving skills training on the severity of aggression in type 1 bipolar disorder patients. Entry criteria: aged 18 to 60 years. Earning the minimum score of 75 from the Bass and Prisons questionnaire in Mashhad. Exit criteria: Absence in problem solving skills training group in more than 25% of its sessions. Failure to perform assignments in the problem solving skill group or lack of accountability for the follow-up required. Method: In this study, 60 patients with type 1 bipolar disorder admitted to Avicenna Hospital in Mashhad were selected by convenience sampling and randomly assigned to two groups of control and intervention. Both groups completed the bass and perry aggression questionnaire as a pretest in the beginning of the treatment plan. Both the intervention and control groups, routine patient training continued, and the intervention group received routine training, received training on problem solving skills in four sessions of 60 minutes for one month. Two months after the completion of the training, both groups completed the Bass and Perry questionnaires as post-tests.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017051633994N1**

Registration date: **2017-09-19, 1396/06/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-09-19, 1396/06/28

##### Registrant information

##### Name

Malihe Eshaghzadeh

##### Name of organization / entity

Mashhad University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3853 1511

##### Email address

eshaghzadehm931@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University Of Medical Sciences

##### Expected recruitment start date

2017-04-04, 1396/01/15

##### Expected recruitment end date

2017-04-21, 1396/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the Impact of Problem-Solving Skills Training on the Aggression Severity in Patients with Type 1 Bipolar Disorders

##### Public title

Investigating the Impact of Problem-Solving Skills Training on the Aggression Severity in Patients with Type 1 Bipolar Disorders

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Entry criteria: aged 18 to 60 years. Earning the minimum score of 75 from the Bass and Prisons questionnaire in Mashhad. Exit criteria: Absence in problem solving skills

training group in more than 25% of its time. Failure to perform assignments in the problem solving skill group or lack of accountability for the follow-up required.

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

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

Randomized

#### **Randomization description**

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

Not blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

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

Mashhad University Of Medical Sciences

##### **Street address**

Daneshgah AVE

##### **City**

Mashhad

##### **Postal code**

#### **Approval date**

2017-03-11, 1395/12/21

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

IR.MUMS.REC.1395.619

## **Health conditions studied**

### 1

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

Bipolar disorder

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

F31.1

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

The patient is currently manic, without psychotic symptoms (as in F30.1), and has had at least one other affective episode (hypomanic, manic, depressive, or mixed) in the past.

## **Primary outcomes**

### 1

#### **Description**

Aggression

#### **Timepoint**

Before the intervention. Two months after intervention

#### **Method of measurement**

Buss-Perry Aggression Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Patients received problem solving skills in 4 sessions, 60 minutes each week with routine training sessions.

#### **Category**

Behavior

### 2

#### **Description**

Control group: Patients received only routine training.

#### **Category**

Behavior

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Mashhad Ebne Sina Psychiatr Hospital

##### **Full name of responsible person**

Mrs Azghandi

##### **Street address**

Street Hurr Ameli

##### **City**

Mashhad

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Research and Technology Mashhad University of Medical sciences

##### **Full name of responsible person**

Vaghee Saeed

##### **Street address**

Nursing Collage

##### **City**

Mashhad

#### **Grant name**

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Research and Technology 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**  
Mashah University Of Medical  
**Full name of responsible person**  
Vaghee Saeed  
**Position**  
MSc  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*