

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Evaluation the impact of psycho education on anxiety, depression and mania in bipolar disorder patients based on mobile application

#### Protocol summary

##### Study aim

Evaluation the impact of psycho education on anxiety, depression and mania in bipolar disorder patients based on mobile application

##### Design

This study was two arms randomized clinical trial. The study population consisted of 60 patients aged 18-60 years who were discharged from Ibn Sina psychiatric hospital in Mashhad. They were randomly divided into two groups of intervention and control based on random number table. Then the software was installed on the cellphone of the intervention group and they were asked to use it for three months.

##### Settings and conduct

The study site is Ibn Sina Psychiatric Hospital in Mashhad

##### Participants/Inclusion and exclusion criteria

Diagnosis of bipolar I or bipolar II disorder Having a compatible smartphone Absence of obvious psychiatric symptoms No alcohol or drug abuse No physical illness at the same time Be literate Adults aged 18 to 60 years

##### Intervention groups

"Intervention group": Educational content of the application was extracted and summarized from a psychiatric book entitled "Bipolar Disorder and Continuing Life" and Medscape site. The application with the name of "Bipolar Disorder and Continuing Life", was designed for the Android operating system in the Android Studio environment using Java language. In the first step, when entering the study depression, anxiety, and mania of all participants were measured using Beck Anxiety Inventory, Beck Depression Inventory, and young Mania Rating Scale. After discharge from hospital, the application "Bipolar Disorder and Continuing Life" was installed on the intervention group' mobile phones. They were asked to use the application for three months.

##### Main outcome variables

Anxiety, Depression, Mania

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190520043645N1**

Registration date: **2020-01-01, 1398/10/11**

Registration timing: **retrospective**

Last update: **2020-01-01, 1398/10/11**

Update count: **0**

##### Registration date

2020-01-01, 1398/10/11

##### Registrant information

##### Name

Bibi Zohreh Hashemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 5700

##### Email address

hashemiz2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-19, 1397/09/28

##### Expected recruitment end date

2019-01-18, 1397/10/28

##### Actual recruitment start date

2018-12-19, 1397/09/28

##### Actual recruitment end date

2019-03-20, 1397/12/29

##### Trial completion date

2019-05-19, 1398/02/29

##### Scientific title

Evaluation the impact of psycho education on anxiety, depression and mania in bipolar disorder patients based on mobile application

**Public title**

Evaluation the impact of psycho education on anxiety, depression and mania in bipolar disorder patients based on mobile application

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of bipolar I or bipolar II disorder according to the criteria in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) Having a compatible smartphone for the 3-month study period  
Absence of obvious psychiatric symptoms (euthymic state)  
No alcohol or drug abuse up to 6 month prior to the study  
No physical illness at the same time  
Be literate  
Sufficient knowledge of the Persian languag  
Adults aged 18 to 60 years

**Exclusion criteria:**

Need for inpatient treatment at the time of recruitment, ,  
Suicidality  
Diagnosis of psychosis , schizophrenia or an intellectual disability

**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: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The current study is a two-group randomized trial with pre-test and post-test design. The method used to randomize the random number table was done by the project partner. As the colleague touches one of the numbers and moves in a predetermined direction, the numbers are recorded and assigned to different groups. Randomization was performed at the first measurement at the individual level. Researchers responsible for collecting data and participants were aware of the group's task after randomization. The researchers who analyzed the data were not aware of the group allocation of participants

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences

**Street address**

The first center of Seven Alavi Gardens, Campus of Medical Sciences ,Kerman

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Approval date**

2018-07-21, 1397/04/30

**Ethics committee reference number**

IR.KMU.REC.1397.241

**Health conditions studied****1****Description of health condition studied**

Bipolar affective disorder

**ICD-10 code**

F31

**ICD-10 code description**

Bipolar disorder

**Primary outcomes****1****Description**

Depression Score in Beck Questionnaire

**Timepoint**

Three months

**Method of measurement**

Beck Depression Inventory

**2****Description**

Anxiety Score in Beck's Inventory

**Timepoint**

Three months

**Method of measurement**

Beck Anxiety Inventory

**3****Description**

Mania score in Young Mania Rating Scale

**Timepoint**

Three months

**Method of measurement**

Young Mania Rating Scale

**Secondary outcomes**

**1**

**Description**

1

**Timepoint**

1

**Method of measurement**

1

**Intervention groups**

**1**

**Description**

Intervention group: Educational content of the application was extracted from a psychiatric book entitled "Bipolar Disorder and Continuing Life". All extracted information were summarized and rewrite in simple language. The educational content was disused in an expert panel consisted of psychiatrists and medical bioinformatic. The 12 main topics of the educational content were pharmaceutical therapy, psychiatry therapy, adolescents, marriage, anxiety management, cognitive bias, irritability, communication skill, focusing on goals, health improvement, definitions of concepts and medications. The application with the name of "Bipolar Disorder and Continuing Life", was designed for the Android operating system in the Android Studio environment using Java language. The 12 main topics of educational content was embedded into the application. Each main menus is subdivided into sub-menus according to the volume and categorization of the contents. To evaluate the initial version of the application several psychiatrists and users were assessed the application. Finally, after troubleshooting, the final version of the application was prepared. The participants were evaluated in two stages. In the first step, when entering the study depression, anxiety, and mania of all participants were measured using Beck Anxiety Inventory, Beck Depression Inventory, and Yankee Mania Rating Scale. After discharge from hospital, the application "Bipolar Disorder and Continuing Life" was installed on the patients' mobile phones.

**Category**

Behavior

**2**

**Description**

Control group: After randomization, per-test was conducted one day before starting the intervention. Participants were assessed depression, mania and anxiety as outcome variable. Also, post-test was performed one day after the end of intervention. The "Bipolar disorder and continuing life" application did not provided to the control group and they received routine

education after discharge.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ibn sina hospital

**Full name of responsible person**

Zohreh Hashemi

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The first center of seven Alavi Gardens, Campus of Medical Science, Kerman Town

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Deputy Director of Research and Technology

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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**

Kerman 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

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## Person responsible for general inquiries

### Contact

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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)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable