

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

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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 language
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

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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****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

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Other areas of specialty/work

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Razavi Khorasan

Postal code**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