

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluating the effect of mobile application-based monitoring in reducing disorder recurrence in bipolar patients

Protocol summary

Study aim

Evaluating the effect of mobile application-based monitoring in reducing disorder recurrence in bipolar patients

Design

A clinical trial with a control group, with parallel groups, randomized using a table of random numbers is performed on 50 patients.

Settings and conduct

In the intervention group, the monitoring software will be installed on the patients' phones and the patients will be taught how to use the software. Patients are prompted with an alarm in the system to perform their daily monitoring. Symptoms that patients should evaluate include mood, sleep duration, medication use. In the control group, patients will use their smartphone for routine communication activities. All patients continue their standard treatment. Then, the patients are visited by a psychiatrist 2 weeks, 6 weeks, 2 months, and 6 months after discharge. The study will be conducted in 22 Bahman Qazvin Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years, having a minimum level of reading and writing, owning a smartphone and diagnosis of bipolar disorder according to DSM-V, discharge following an episode from a psychiatric hospital. Exclusion criteria: pregnancy, substance use, lack of Persian language skills, and lack of consent to participate in the study

Intervention groups

The intervention group installs the software on the patient's phone at the time of discharge, and after discharge, symptoms of disease recurrence and re-hospitalization are monitored in predetermined visits. In the control group without installing the software, symptoms of disease recurrence and re-hospitalization are monitored.

Main outcome variables

Re-hospitalization rate and duration of re-hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230305057617N1**

Registration date: **2023-04-13, 1402/01/24**

Registration timing: **prospective**

Last update: **2023-04-13, 1402/01/24**

Update count: **0**

Registration date

2023-04-13, 1402/01/24

Registrant information

Name

Zahra Arabyazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3355 5054

Email address

za.yazdi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of mobile application-based monitoring in reducing disorder recurrence in bipolar patients

Public title
The effect of software monitoring on relapse of bipolar disease

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having a minimum level of literacy Having a smartphone
Diagnosis of bipolar disorder according to DSM-V
Discharge following an episode (depression, mania, or mixed episode) from a psychiatric hospital
Exclusion criteria:
pregnancy substance use Lack of Persian language skills
Lack of consent to participate in the study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is simple. The unit of randomization is individual and its tool is a table of random numbers. Creating a random sequence using web randomization. Concealment is done by central randomization method.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Making mobile phone software

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

22bahman hospital; Pastor Alley; Rahahan Street

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2022-07-20, 1401/04/29

Ethics committee reference number

IR.QUMS.REC.1401.105

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

The rate of readmission

Timepoint

Patients are visited by a psychiatrist 2 weeks, 6 weeks, 2 months, and 6 months after discharge, and the use of the software is checked with available charts and the study objectives are checked with questionnaires.

Method of measurement

Use of patients' electronic files

2

Description

Duration of re-hospitalization

Timepoint

Patients are visited by a psychiatrist 2 weeks, 6 weeks, 2 months, and 6 months after discharge, and the use of the software is checked with available charts and the study objectives are checked with questionnaires.

Method of measurement

Use of patients' hospitalization records

Secondary outcomes

1

Description

Recurrence of depressive symptoms

Timepoint

Patients are visited by a psychiatrist 2 weeks, 6 weeks, 2 months, and 6 months after discharge

Method of measurement

Hamilton Depression Rating Scale

2

Description

Recurrence of mania symptoms

Timepoint

Patients are visited by a psychiatrist 2 weeks, 6 weeks, 2 months, and 6 months after discharge

Method of measurement

Young Mania Rating Scale

3**Description**

General health status

Timepoint

Patients are visited by a psychiatrist 2 weeks, 6 weeks, 2 months, and 6 months after discharge

Method of measurement

General Health Questionnaire

Intervention groups**1****Description**

Intervention group: First, the monitoring software will be installed on the patients' phones and the patients will be taught how to use the software. Patients are prompted with an alarm in the system to perform their daily monitoring. The symptoms that patients should evaluate on a daily basis will include mood, activity level, sleep duration, and drug consumption. For the convenience of patients, this system will be designed in Persian language and will be available to patients.

Category

Rehabilitation

2**Description**

Control group: In the control group, without installing the software, they are visited the same as the control group, and the symptoms of the disease are monitored by a questionnaire.

Category

Rehabilitation

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

22Bahman hospital

Full name of responsible person

Zahra Arabyazdi

Street address

22bahman Hospital; Pastor Alley; Rahahan Street

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3355 5054

Email

hospital.bahman@yahoo.com

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

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mahdi Mirhashemi

Street address

Qazvin University of Medical Sciences; Shahid Bahonar Blvd

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3333 6001

Email

medicine@qums.ac.ir

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

Zahra Arabyazdi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

22Bahman Hospital; Pastor Alley; Rahahan Street

City

Qazvin

Province

Qazvin
Postal code
3419759811
Phone
+98 28 3355 5054
Email
Za.yazdi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Zahra Arzbyazdi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
22Bahman Hospital; Pastor Alley; Rahahan Street
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3355 5054
Email
Za.yazdi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person

Zahra Arzbyazdi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
22Bahman Hospital; Pastor Alley; Rahahan Street
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3355 5054
Email
Za.yazdi@gmail.com

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

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

Data Dictionary

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