Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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