

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Development and evaluation of a web-based tool to improve quality of life and drug compliance in patients with bipolar disorder

Protocol summary

Increase drug compliance; Improve patients' quality of life

Study aim

Design and Development of an application for Symptom Monitoring in Patients with Bipolar Disorder to Increase drug compliance and Quality of Life

Design

Clinical trial without control group

Settings and conduct

first an application design that monitors daily mood, sleep, energy, irritability, and drug use with 6 short questions and advises to visit treatment center if there are significant changes. The study will be performed on patients with bipolar I disorder who are admitted to the Iran Psychiatric Hospital from December 22.2019 to 4 February 2020. Patients are treated with standard medication at the time of admission. Patients in the intervention group, after discharge and 3 months use of application, will be visited in the hospital clinic by a psychiatrist for 30 minutes and interviewed for feedback.

Participants/Inclusion and exclusion criteria

Diagnosis of Bipolar Disorder, Patient hospitalization at the time of Inclusion in the study, Individual consent and legal guardianship to participate in the study, At least elementary education, Ability to use and work with software, Smartphone access, Ages 18 to 60 years; not: Serious physical illness, Pregnancy, Obsessive-compulsive disorder

Intervention groups

before the discharge of the intervention group patients, an application that built by the research team, will be installed on the patients' smartphones. Patients will be educated how to work with the application. Patients will log in to the app on a daily basis after discharge, and answer the questions in the software. A chart of mood and sleep changes in the past few days, will available for them. Information is also entered online into the admin panel, which is available to the research team. Patients work with this app for three months and will be interviewed for feedback after three months.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190814044531N1**

Registration date: **2019-12-20, 1398/09/29**

Registration timing: **prospective**

Last update: **2019-12-20, 1398/09/29**

Update count: **0**

Registration date

2019-12-20, 1398/09/29

Registrant information

Name

Amir hossein Jalali nodoushan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 3991

Email address

jalali.ah@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and evaluation of a web-based tool to improve quality of life and drug compliance in patients with bipolar disorder

Public title

Development and evaluation of a web-based tool to improve quality of life and drug compliance in patients with bipolar disorder after discharge

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of Bipolar Disorder Based on Clinical Interview
Patient hospitalization at the time of Inclusion in the study
Individual consent and legal guardianship to participate in the study
At least elementary education
Ability to use and work with software
Smartphone access within 3 months follow-up
Ages 18 to 60 years

Exclusion criteria:

Serious physical illness
Pregnancy
Obsessive-compulsive disorder according to DSM-5 criteria
Inability to learn how to use smart phone software
Unwillingness to participate in the study

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **30****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of iran university of medical sciences

Street address

Iran Educational-Therapeutic Psychiatric Center, 7th km of Karaj Special Road, before Azadegan Ring Road, next to the gas station, behind Shahid Tondgooyan Parking

City

Tehran

Province

Tehran

Postal code

1398913151

Approval date

2019-04-20, 1398/01/31

Ethics committee reference number

IR.IUMS.FMD.REC.1398.076

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**

Feedback from patients using the application

Timepoint

3 months later

Method of measurement

Clinical Interview

Secondary outcomes

empty

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

Intervention group: In this study, before the discharge of the intervention group patients, an application that designed and built by the research team, will be installed on the patients' smartphones and a user number will be defined for them. Patients will be educated how to work with the application. Patients will log in to the app on a daily basis after discharge, and answer the questions in the software. A chart of mood and sleep changes in the past few days, will available for them According to the questions answered. Information is also entered online into the admin panel, which is available to the research team.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Educational-Therapeutic Psychiatric Center

Full name of responsible person

Amir Hossein Jalali Nodoushan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abas Motevalian

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN

City

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admins@iums.ac.ir

Web page address

<http://iums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Amir hossein Jalali nodoushan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Web page address

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Amir hossein Jalali nodoushan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

zahra akashe

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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akashe_z@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

To protect patients' privacy

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study protocol, informed consent form, and clinical
trial report will be shared. But patients' personal and
identity information will not be released.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific
institutions

Under which criteria data/document could be used

Using information and data to manage and follow up
psychiatric patients with lowest cost

From where data/document is obtainable

Dr. Amir Hossein Jalali Nodushan, Dr. Kaveh Alavi Iran
Psychiatric Hospital

What processes are involved for a request to access data/document

Six months after publishing the results, contacting Dr.
Jalali to the Iran Psychiatric Hospital will be helpfull.

Comments