Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

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

Protocol summary

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
Increase drug compliance; Improve patients' quality of life

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
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: **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
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Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN
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adminsite@iums.ac.ir
Web page address
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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
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
Street address
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Person responsible for scientific inquiries

Contact
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Amir hossein Jalali nodoushan
Position
Assistant Professor
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Specialist
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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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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