



The Investigation of the Effectiveness of Mobile-based Psychoeducation in Patients with Bipolar Disorder: A Randomized Controlled Trial (RCT)

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Abstract

Background: Bipolar disorder is a chronic and debilitating psychiatric condition. Mobile-based psychoeducation is a very important tool for the treatment of this disorder.

Objectives: The study aimed to provide scientific evidence regarding the effectiveness of these tools for patients with bipolar disorder.

Methods: In a randomized control trial (RCT) with a sample size of 41, the participants were randomly assigned to one of the intervention or the control arms based on the random number table. The study was performed in a psychiatric teaching hospital in Mashhad, Iran. The primary targets of the study was to measure the depression, manic, and anxiety symptoms that were measured at baseline and 3 months follow-up for the intervention and the control group. A mobile application was developed and provided to the intervention group after discharge from the case hospital. The control group did not receive the application and received routine health care services during the study. A baseline comparison was performed between the groups, comparisons of the primary outcomes between the groups and within each group were carried out.

Results: The results showed that the score of anxiety, depression, and mania at baseline and after the follow-up did not have a significant decrease within the groups. In addition, a slight reduction in the depression and anxiety scores within the groups was found. The mean of anxiety (P-value: 0.035), depression (P-value: 0.024), and mania (P-value: 0.007) after 3 month follow-up had a significant decrease between the groups. A baseline comparison was performed between the groups, and comparisons of the primary outcomes between the groups and within each group were carried out.

Conclusions: Given the low effectiveness of using mobile-based psychoeducation on anxiety, depression, and mania in bipolar patients. It is recommended to use mobile applications as a complementary treatment along with other types of treatment for bipolar patients in future studies to obtain more evidence about the effectiveness of mobile-based psychoeducation.

Keywords: Applications, Mobile Health, Bipolar Disorder, Psychoeducation

1. Background

Bipolar disorder is a chronic and debilitating psychiatric condition. About one in 100 people in the world will be affected by mental or neurological disorders at some point in their lifetime (1). The World Health Organization (WHO) in 2009 listed bipolar disorder as the sixth leading cause of disability among 14-55-year-old people (2). In Iran, the prevalence of type I and type II of bipolar disorder have been estimated to be around 0.04% and 3%, respectively (3).

Bipolar disorder is often hereditary, and genes play a role in its development. Suicide is the worst consequence of bipolar disorder in the depression phase (1, 4). In severe cases, suicide rates of up to 15% have been reported (5). Poor economic conditions, unemployment, being fired from work, marital conflict, dropping out of school, and many re-hospitalizations in the psychiatric hospital are other complications of bipolar disorder. Interventions such as correct use of medications, social and family sup-

port, use of communication and problem-solving skills, and psychotherapy have been proven to be helpful for individuals with bipolar disorder to prevent recurrence of bipolar disorder (1). Although the use of medication, and especially lithium, is a necessary medication for the treatment of bipolar disorder, most people prefer not to use medication. The results of some studies show that at least one-third of patients with bipolar disorder do not use more than 70% of their medication (1, 6, 7). Moreover, despite pharmacological therapy, the recurrence rate of bipolar disorder is high (8). Therefore, non-pharmacological therapy alongside pharmacological therapy seems necessary.

One of the most important non-pharmacological treatments for bipolar disorder is “psychoeducation” (9). Psychoeducation is an educational method that provides information on the nature of mental disorders, including etiology, treatment methods, outcomes, prognosis, progression, recurrence, etc. Psychoeducation can be delivered to patients, their families, or both (10). This approach can improve families’ awareness about mental disorders (11). There are some studies regarding the effectiveness of psychoeducation programs in reducing symptoms and recurrence of mental disorders. As well, psychoeducation can improve the quality of life of patients with mental disorders (6, 12). If this training is delivered through a mobile phone application, the satisfaction and acceptance of patients with this treatment will be doubled (13).

Mobile applications can be used as cost-effective, accessible, and user-friendly tools for psychological interventions and training (14, 15). Mobile-based psychoeducation has advantages compared to traditional methods (face-to-face counseling), including easy access to psychiatric training and anonymity guaranteed (16). In recent years, plenty of studies have examined the application of mobile-based psychoeducation and the use of a mobile phone for the education of bipolar patients (9, 17-19). In Iran, despite the effectiveness of psychoeducation on bipolar disorder treatment, effective psychoeducation services are not yet available after bipolar disorder recovery (20).

As discussed before, mobile-based psychoeducation is a very important method for the treatment of bipolar disorder. As well, mobile applications can be used to deliver educational interventions.

2. Objectives

Therefore, the current study was conducted in order to provide evidence regarding the effectiveness of mobile ap-

plications in patients with bipolar disorder.

3. Methods

3.1. Study Design

This study was a randomized controlled trial (RCT) study (code: IRCT20190520043645N1). The study was carried out in autumn and winter in 2018 - 2019.

3.2. Study Setting

The study was performed in Ebnesina and Dr. Hejazi’s Psychiatric Hospital and education center affiliated to Mashhad University of Medical Sciences. The case hospital is a referral psychiatry center in the eastern and north-eastern regions of Iran. This center offers psychological health care services to patients with mental diseases, including bipolar disorder.

3.3. Study Participants and Sample Size

The eligibility inclusion criteria were as follows: 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) (18). Adults aged 18 to 60 years, sufficient knowledge of the Persian language, having a compatible smartphone for the 3-month study period (i.e. smartphone with Google™’s Android operating system version 4.4), basic competence in using mobile devices, absence of obvious psychiatric symptoms (euthymic state), no alcohol or drug abuse up to 6 months prior to the study, no physical illness at the same time, as well as being literate. Exclusion criteria were the need for inpatient treatment at the time of recruitment, suicidality, and diagnosis of schizophrenia or an intellectual disability.

The current study was approved by the Research Ethics Committee of Kerman University of Medical Sciences (ethics code: IR.KMU.REC.1397.241). Patients were screened according to the inclusion criteria for the study to ensure eligibility. The researchers explained briefly the aims of the study, the intervention to eligible patients and asked the participant if they were interested. All eligible participants provided written consent prior to participation.

The application was installed in patients’ smartphones by the researchers, and a brief explication of the application was provided. A system tutorial was designed for the application for help to the patient during the study. Additionally, a telephone number was provided to contact the researchers for further support.

3.4. Randomization

The current RCT was a two-armed design. Participants randomly gave a number from 1-60 and randomly were assigned to either the intervention or the control group. The participants and the experimenters were not blinded in the current study. The researchers who conducted data analysis were not aware of the group allocation of the participants.

3.5. Intervention and Measurements

Primary outcome measures were depression, manic, and anxiety symptoms that were measured at baseline and follow-up for the intervention and control group. The application “bipolar disorder and continuing life” was installed on the participants’ mobile in the intervention group after discharge from the hospital. The participants were taught how to use the application. They were asked to use the application for three months and try to use all the topics provided in the application. The control group did not receive the application and received routine health care services during the study. After three months, all participants were invited to participate in the second phase of the study. The data collection instruments were three questionnaires at baseline and after three months. At the end of the study, when the two groups completed the questionnaires (three months follow up) and data gathering was completed, the application was installed on the mobile of the volunteer participants in the control group. The data collection instruments are described below:

Manic symptoms were assessed using the validated Persian version of the Beck Depression Inventory (BDI) version 2. The original version of this questionnaire was developed by Beck et al. (21) in 1961 and was updated in 1996 to measure three important aspects of depression, including feelings about the future, loss of motivation and expectations. This self-report questionnaire was designed to measure the depression of people aged 13 to 80 years. The BDI questionnaire consists of 21 self-assessment multiple-choice questions whose items include depression symptoms (such as hopelessness and irritability), cognitive symptoms (such as guilt and feelings of being punished), physical symptoms (such as fatigue, weight loss, and lack of interest in sex). A four-point Likert scale of 0 to 3 was used to answer each question. The maximum score was 63, which indicates severe depression (21). The Persian version has high validity ($P < 0.001$, $r = 72\%$), reliability ($P < 0.001$, $r = 83\%$), and internal consistency ($\alpha = 92\%$) which indicates the appropriateness of this instrument for

clinical and research evaluations in the Iranian population (22, 23).

The Beck anxiety inventory (BAI) is a self-report instrument that is used to measure the severity of anxiety in children and adults. BAI was suggested by Aaron Temkin Beck in 1990 (24). The BAI consists of 21 questions, asking about common anxiety symptoms experienced during the past week such as numbness, tingling, sweating not due to heat, and fear of the worst happening. Beck’s Anxiety questionnaire was translated into Persian and was validated by Kaviani and Mousavi (24). The results of this study showed that BAI is a valid ($P < 0.01$, 74%), $r = 0.72$) and reliable ($P < 0.01$, $r = 84\%$) instrument for clinical and research evaluations in the Iranian population (24). The validated Persian version of BAI was adopted in the current study for anxiety assessment.

Young Mania Rating scale (YMRS) was suggested by Satatovic et al. in 1978. YMRS the questionnaire has 11 items to evaluate manic symptoms (25, 26). The YMRS is a self-administrated instrument based on the patient’s subjective report of his or her clinical condition over the previous 48 hours. The maximum score is YMRS 50. Values less than 12 indicate the patient’s recovery period and value equal and more 12 than demonstrating the acute phase of the disease (25, 26). In the current study a validated Persian version of YMRS questionnaire was adopted that had high validity ($P = 0.01$, $r = 74\%$) and reliability ($P < 0.01$, $r = 82\%$) rate in the Iranian population (12, 27).

3.6. Preparing Educational Content

The psychological and self-care training materials were provided for patients with bipolar disorder after discharge. The educational content of the application was extracted from a psychiatric book entitled “bipolar disorder and continuing life” (1). This book was written in Persian, and the target population of this book are Iranian patients with bipolar disorder. All extracted information was summarized and rewritten in simple language. The educational content was discussed in an expert panel consisted of psychiatrists and medical informatics specialists. The 12 main topics of the educational content were pharmaceutical therapy, psychiatric therapy, adolescents, marriage, anxiety management, cognitive bias, irritability, communication skill, focusing on goals, health improvement, definitions of concepts, and medications.

3.7. Application Design

An application was designed based on the Android operating system in the Android Studio environment using

Java language. The 12 main topics of educational content were embedded in the application. Each main menu was 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 assessed the application. Finally, after troubleshooting, the final version of the application was prepared.

3.8. Statistical Analysis

The characteristics of two groups at baseline were compared using student's *t*-test for continuous variables, the chi-square test was used for categorical variables. A paired *t*-test and independent *t*-test was conducted to compare the score of primary outcome measures within groups and between groups at baseline and after three months follow-up in the groups, respectively. Data were analyzed using SPSS 11 software. A significance level of 0.05 was considered in all tests.

4. Results

Thirteen and six eligible participants were lost in the follow-up in the intervention and control group, respectively. The response rate of the study was 68.3%. Reasons for lost follow-up included readmission of the patient during the study (exit criteria), unwillingness to continue cooperation, and loss of mobile phone. Finally, out of 60 participants, 17 and 24 of them were included in the analysis as the intervention and control group, respectively.

Table 1 shows the baseline characteristics of the participants. The groups were similar in gender distribution (P-value: 0.406, chi-square test). A significant difference in variables of age was observed in the groups (P-value < 0.001, student's test). The current study was conducted in a psychiatric hospital, the significant difference in the frequency of age was not considered in the statistical analysis.

The results of data analysis showed that most of the participants were 20 - 30 years old (39%) and had an education level of less than high school (43.9%). Moreover, more than half of them were females (53.7%) (Table 1). Figure 1: shows the CONSORT diagram and its application in this study. Table 1 shows the baseline characteristics of the participants.

4.1. Baseline Characteristics of the Participants

The results of paired sample *t*-test tests showed that the score of anxiety, depression, and mania at baseline, and after three months follow-up did not have a significant de-

Table 1. Baseline Characteristics of the Participants

Variables	Intervention Group, No. (%)	Control Group, No. (%)
Age		
≤ 20	0	1 (4.2)
21 - 30	11 (64.7)	5 (20.8)
31 - 40	5 (29.4)	9 (37.5)
41 - 50	1 (5.9)	7 (29.2)
> 50	0	2 (8.3)
Gender		
Female	10 (58.8)	12 (50)
Male	7 (41.2)	12 (50)
Education		
High school	5 (29.4)	13 (54.2)
Diploma	8 (47.1)	9 (37.5)
Bachelor	4 (23.5)	2 (8.3)
Hospitalization days		
≤ 10	2 (8.4)	3 (17.6)
11 - 20	7 (29.1)	2 (11.7)
21 - 30	10 (41.6)	9 (52.9)
31 - 40	2 (8.4)	0
> 40	2 (8.4)	3 (17.6)
Marital status		
Single	6 (25)	10 (58.8)
Married	16 (66.6)	5 (29.4)
Divorced	2 (8.4)	2 (11.7)

crease within the intervention and control group. However, a slight reduction in the scores of depression and anxiety within the groups was found. As well, the same results were found in the mean of anxiety, which improved to a 7.24 score. The mean of anxiety in the intervention and control group were -4.83 (SD: ± 12.48) and 2.41 (SD: ± 12.42), respectively. In the mean of mania that it increased the score by 4.54. Table 2 shows a comparison between outcome variables at the 3-month follow-up within groups.

Comparison between outcome variables at the 3-month follow-up within and between the groups

Results of independent *t*-tests demonstrated that at baseline, a significant difference in the score of depression (P-value: 0.07), anxiety (P-value: 0.55), and mania (P-value: 0.65) was not observed.

Our results of independent *t*-tests showed that the score of anxiety (P-value: 0.02), depression (P-value: 0.02), and mania (P-value: 0.003) after 3-month follow-up had a

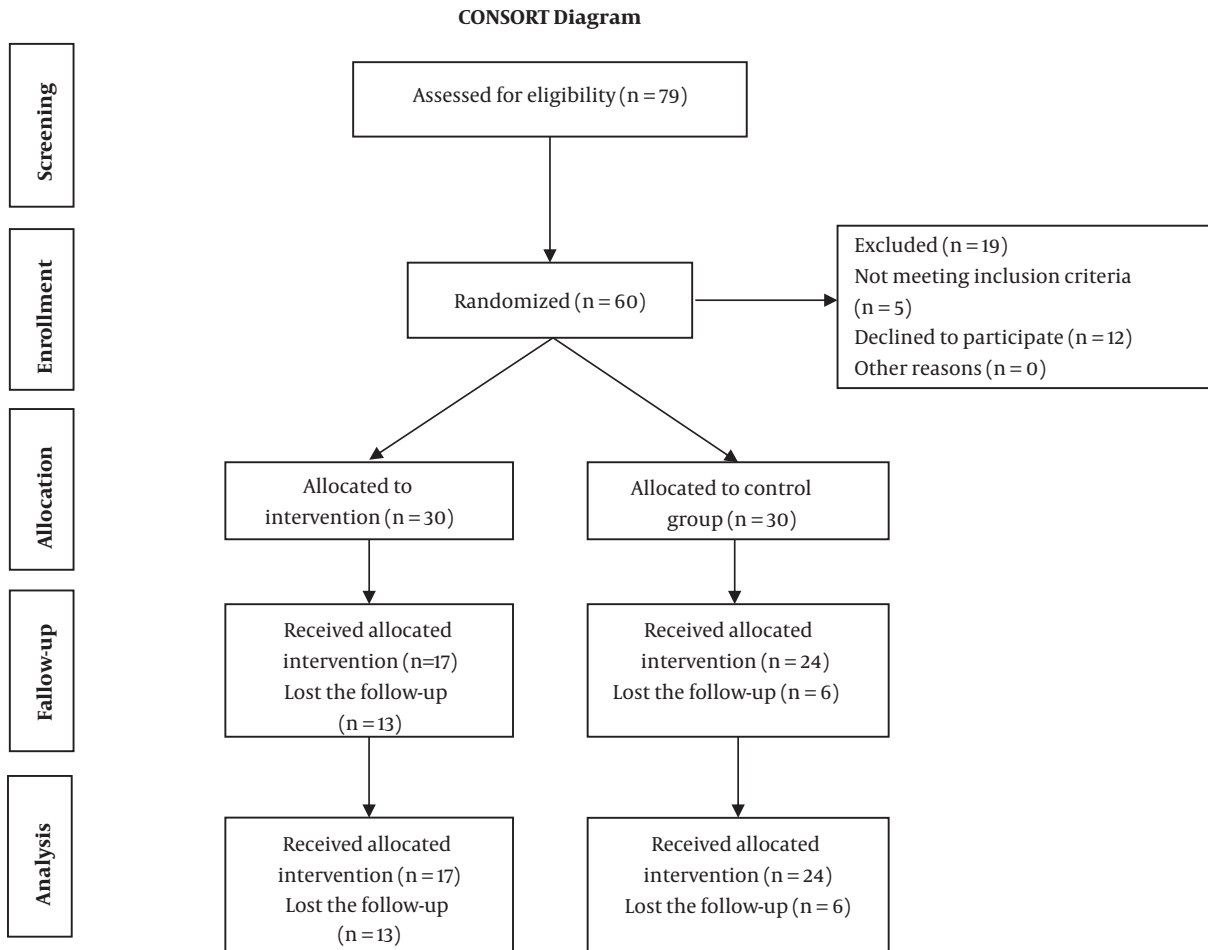


Figure 1. CONSORT diagram

Table 2. Comparison Between Outcome Variables at Baseline and After Follow-up Within Groups

Outcome Variables	Intervention Group		Control Group	
	Difference of Mean \pm SD at Baseline	P-Value	Difference of Mean \pm SD After Follow-up	P-Value
Anxiety	2.41 \pm 12.42	0.43	-4.83 \pm 12.48	0.07
Depression	-1.70 \pm 9.84	0.48	-5.54 \pm 15.50	0.09
Mania	2 \pm 5.51	0.15	-2.54 \pm 7.05	0.09

significant decrease between the intervention and control group. Participants in the intervention group who were compared to the control group reported a decrease in the mean of anxiety (mean: 5.38, SD: 1.90), depression (mean: 11.01, 95%, SD: 4.69), and mania (mean: 9.90, SD: 4.53) score.

Table 3 shows a comparison between outcome vari-

ables at the 3-month follow-up between groups.

5. Discussion

The purpose of this RCT study was to evaluate the effectiveness of mobile-based psychoeducation on anxiety,

Table 3. Comparison Between Outcome Variables at the 3-Month Follow-up Between Groups

Outcome Variables	Intervention Group		Control Group	
	Measuring Time	Mean (Standard Deviation)	Mean (Standard Deviation)	P-Value
Anxiety	Baseline	13.59 (11.92)	16.25 (15.39)	0.55
	After follow-up	11.18 (9.58)	21.08 (16.83)	0.02
Depression	Baseline	10.12 (7.27)	17.29 (14.84)	0.07
	After follow-up	11.82 (11.52)	22.83 (16.71)	0.02
Mania	Baseline	5.41 (6.15)	6.25 (5.64)	0.65
	After follow-up	3.41 (3.39)	8.79 (7.28)	0.003

depression, and mania symptoms in patients with bipolar disorder. The important findings of the present study will be discussed in the following paragraphs.

The first finding of the present study was that mobile-based educational applications can reduce the mania score of patients. These findings tie well with previous studies. The results of the study by Keck et al. (28) found out psychiatric training alongside pharmaceutical therapy for both the symptoms of mania and depression in patients with bipolar type I had positive impacts. As well, a study conducted by Ghoushchian (29) in Iran, showed that providing psycho-family complementary therapies and pharmaceutical therapy was very effective in controlling mania symptoms. Although these studies are in line with the findings of the present study and confirm the effectiveness of psychotherapy training along with pharmaceutical therapy to reduce the mania symptom in patients with bipolar disorder, none of the above studies, despite the smartphone penetration in recent years, have used this technology in the education of patients with mental disorders. Therefore, our research provides major findings in this field.

A second important finding of the present study was the effectiveness of mobile-based education in reducing anxiety in patients with bipolar disorder. Our findings showed a decrease of 2 scores on average in anxiety scores. In line with the results of this study, numerous studies have demonstrated the impact of mobile application on reducing anxiety symptoms (30, 31).

Joseph Firth, in a meta-analysis confirmed the effectiveness of psychological interventions through smartphone devices in reducing anxiety symptoms (32). The results of another study in Finland on 15 university staff showed that users of Ovia stress management applications found the application useful and acceptable (33). In Italy, Gaggioli et al. (34) found that a mobile application was useful in reduc-

ing the level of psychological stress, reducing arousal, increasing post-workout happiness, and lowering the heart rate of users.

The third important finding of the present study was the low effectiveness of the mobile-based educational application on depression of patients with bipolar disorder. In contrast with the findings of our study, Birney et al. (35) also in a study examining the effectiveness of the Mood Hacker application on 300 employees with moderate depression; found that this application had a significant effect on depression symptoms, absenteeism from work, and job stress. Roepke et al. (36) investigated the effectiveness of the Super Better application on depression symptoms. Their results highlighted that patients who used the mobile application reported lower depression scores compared to the group using the online cognitive-behavioral therapy program.

Contrary to our findings, Faurholt-Jepsen et al. (37), in a study aimed to determine whether daily electronic self-monitoring using a smartphone reduces manic symptoms and depression in patients with bipolar disorder, found that daily self-monitoring using the smartphone had no effect on depression and the patients using the application had more persistent depression symptoms compared to control group (37). Reid et al. (38) carried out a randomized controlled trial to examine a mobile phone application for the assessment and management of youth mental health problems in primary care. The results of this study showed that monitoring mental health symptoms appears to increase emotional self-awareness, but mental health symptoms (depression, anxiety, stress) did not change significantly in the intervention group (38).

Most of the above-mentioned studies confirmed the results of our study that the use of mobile-based educational applications could reduce depression, anxiety, and mania in patients with bipolar disorder. It seems, using mobile-

based educational applications could have some benefits such as no need for face to face visits, reducing the psychiatrists' workload, saving time and cost, and encouraging people to use self-management programs. Moreover, our results provide strong evidence about the application of health information technology in the treatment of patients with mental disorders.

5.1. Strengths and Weaknesses of the Study

To our knowledge, the focus of most previous studies in Iran that examined the use of mobile applications on health was on mental disorders (general), and they did not focus on patients with bipolar disorder. This study is the only RCT study that focused on these patients.

5.2. Limitations

The main limitation of the present study was the short time of follow-up, and cost constraints meant that we could not develop an interactive application; therefore, it was not possible for patients to communicate with the therapists through the application.

5.3. Conclusions

The results of this study showed the effectiveness of using the psychological education application on anxiety, depression, and mania in bipolar patients. Therefore, it is recommended to use the mobile applications as a complementary treatment along with other types of treatment for bipolar patients and to encourage patients to use the applications.

Since mental disorders encompass a wide range of illnesses and disorders and in this study, only the effect of mobile-based education on the symptoms of depression, anxiety, and mania in bipolar patients was assessed, it is recommended that similar studies are conducted for other mental disorders.

Footnotes

Authors' Contribution: Study concept and design and acquisition of data: Zohreh Hashemi. Analysis and interpretation of data: Malihe Ziaee. Drafting of the manuscript: Zohreh Hashemi and Zahra Ebnehoseini. Critical revision of the manuscript for important intellectual content: Roghayeh Ershad Sarabi. Statistical analysis: Maliheh Ziaee. Administrative, technical, material support, and study supervision: Afshin Sarafinejad and Farzad Akbarzadeh.

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