Original Article

The use of a smartphone app for self-monitoring by patients with bipolar disorder being treated in a primary care setting

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Abstract

Background: Self-monitoring and self-management are growing phenomena in the care of chronic illnesses, like bipolar disorder. A significant fraction of patients with bipolar disorder are cared for by primary care providers. The use of smart technology may be effective in this setting. **Method:** KIOS-Bipolar, a smartphone app that proved superior in a randomized, controlled trial, was beta-tested for two-month periods in 12 patients with bipolar disorder who were under the care of a primary care clinic. **Results:** Adherence to the app was 100%. Patients experienced improvements in depressive (−41%) and manic (−46%) symptoms and overall instability (−39%). Patients felt that the system was user-friendly with an average system usability score of 80.8 (range 48–100). Five participants (41.8%) gave a system usability score ≥ 90. **Discussion:** This open trial suggests that utilization of a self-management tool may be a useful adjunct in the treatment of patients with bipolar disorder in the primary care setting.

Keywords: App, bipolar, self-monitoring

Introduction

Bipolar disorder (BD) is a serious, episodic, life-long mood disorder that affects nearly 2% of the world population.[1,2] Over a third of patients with bipolar illness are treated in the primary care setting.[3] But, independent of treating specialty, and despite advances in its treatment,[3] patients with BP continue to suffer through relapses with concomitant disability and reduction in the quality of life.[4-6] Psychoeducation and early recognition of mild preliminary symptoms prior to the onset of episodes (sometimes referred to as "roughening") are considered of paramount importance in the management of BD.[7,8] Recognition of roughening may be amenable to electronic monitoring and some authors have suggested that the development of new electronic technologies has created an opportunity to address these challenges in mental health.[9] The use of technology and software for monitoring and self-management has shown utility in other medical illnesses such as hypertension and diabetes.[10,11]

Availability and use of mental health applications (apps) have increased over the past few years.[12,13] Unfortunately, a recent

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comprehensive review found that most of the available apps are not supported by scientific validity justifying their use.[14] Specifically, most apps do not monitor predictors of relapse such as inability to sleep, are not validated to augment proper clinical practice, do not have appropriate privacy policy, or adequately cite their information. There is a significant gap between the unmet need for evidence-based self-monitoring and self-management tools for BD and the current stock of available apps.[15,16]

Recently, a patient-centered smartphone app for bipolar disorder was developed based on concepts of nonlinear systems (chaos) theory that aims at monitoring and assisting BD patients in managing their symptoms.[17] The app was developed, in part, with funding from the National Institute of Mental Health. The ensuing system, a smartphone app called KIOS-Bipolar, tracks multiple interacting symptoms as they evolve over time to determine the exact mood state of the patient and establish a behavioral trajectory. Once a patient is established with the app, specific advice is generated to aid the subject with disease management. KIOS-Bipolar also provides analytics that can be used by clinicians and researchers to track outcomes and course of illness. In the initial randomized, controlled study, which was performed in three university psychiatric clinics across the United States, KIOS-Bipolar was associated with increased adherence over a one-year period of time compared to other apps.[18]

The role of primary care providers (PCPs) in caring for psychiatric patients is expanding, and nearly three-quarters of psychiatric patients[19] and a third of all bipolar patients are cared for by PCPs.[3,20] The current study evaluated the use of the KIOS-Bipolar app in the setting of a primary care clinic in a small town to determine the utility and acceptance of this tool when the healthcare provider is not a psychiatrist.

Methods

Study design

This was a beta test of the KIOS-Bipolar app. It was performed in a general medical clinic in Paducah, Kentucky (Cecil Clinic), which was known locally to provide psychiatric services to patients, but did not employ any psychiatric providers. The study was an open-label 8-week study of the app (hhtps://Kiosbipolar.com) to determine its usability, acceptability, and identify barriers to use in the general medicine setting.

Participants

Twelve patients with an established diagnosis of BD were recruited from the pool of patients attending the general clinic. Patients had to be age ≥18 years, able to understand and agree to the study and review and sign informed consent. Participation in the beta test did not impact or alter the study participant's routine clinical care. Patients were provided with KIOS-Bipolar app free of charge through the Internet. If patients did not have a smartphone, a tablet was provided to them. Technical assistance for accessing KIOS-Bipolar was provided through blogs, YouTube videos, and telephone support via the sponsor. Patients were excluded if they were unwilling or unable to comply with study requirements.

All patients provided informed consent, and the study was reviewed and approved by BioMed IRB (San Diego, California, protocol number 2017-4-1-PK). Because this was a single site study, it was not registered with ClinicalTrials.gov.

Assessments

Study participants were asked to complete the online KIOS assessment questionnaire a minimum of two times per week but could complete it daily. The eight items in the questionnaire were derived from the self-assessment version of the Bipolar Inventory of Symptoms Schedule (BISS) [Table 1].[17,21]

At the end of the trial, patients were asked to complete a usability survey. Notes from the patients regarding the ease/benefits of use and hindrances were collected. Subjects were asked to self-report how much completing the KIOS assessments contributed to their self-awareness, attitude, and overall sense of satisfaction with their health status. Examples were encouraged.

Data were also collected from the participant's healthcare provider or other appropriate personnel. They were asked to complete a questionnaire to determine the usefulness and appropriateness of the information provided. This survey included open-ended questions asking for suggestions for future improvements.

Analysis

The primary outcome measure was user satisfaction and patterns of adherence and attrition for KIOS. Secondary outcome measures were composite ratings in depression, mania, and instability at 7 days, 14 days, 30 days, and 60 days. Change in "KIOS score" which is a composite of depression, mania, and instability was also used. Change in KIOS, mania, depression, and instability scores was compared to the NIH trial of KIOS-Bipolar. Descriptive statistics were used.

Results

Adherence to the app in this preliminary assessment was 100%. Data entry procedures took less than 5 min per session with most subjects completing their entries in 2 min. Secondary measures revealed an improvement in all symptoms over the two months of the study [Table 2]. Similar improvements were seen in composite depression (−41%), mania (−46%), and instability (−39%) [Figure 1]. These improvements were reflected in KIOS composite score which was reduced by 25% after 1 week, and 41% reduction at 60 days [Figure 2]. While this was not a randomized trial, the raw scores at the study end were comparable to those seen at the end of the randomized trial done previously (depression: 2.96 vs. 2.69; mania: 1.78 vs. 1.67; and instability: 3.33 vs. 3.27 [all current vs. previous randomized trial]).[18] Patients felt that the system

was user-friendly with an average system usability score of 80.8 (range 48–100). Five participants (41.8%) gave a system usability score ≥ 90 [Figure 3].

Participants provided feedback regarding the use of characteristics of the app [Table 3]. The app had an audio feature in which advice or feedback was provided by an audible voice. Eight patients (67%) used the audio feature, but only one (8%) used it exclusively. It also had a downloadable report, but only 58% used this feature. Ten patients (83%) used the positive behavior checklist provided by the app. Other characteristics were generally rated positively [Table 3].

Participants had an opportunity to provide unguided feedback. Half of the subjects did not choose to do so. Four provided only positive feedback (Great product; I loved using KIOS, it helped me keep my state of mind in further check; I really loved this study, it showed me my strengths and weaknesses; helpful

Table 1: KIOS online assessment questionnaire which the patients completed weekly. Each item was rated on a 7-point scale from "Not at all" to severely

Item	Question
Sadness	Have you felt depressed, sad, or down?
Pessimism	Have you been discouraged, pessimistic, or felt hopeless?
Slowed down	Have you felt slowed down?
Irritability	Have you felt easily irritated, angry, or resentful?
Reduced need for sleep	Were there nights you needed less sleep than usual?
Energetic	Have you had more energy than usual to do things?
Lability	Have your emotions shifted fairly suddenly at times?
Anxiety	Have you felt tense or anxious?

Table 2: Change in the eight monitored items of the BISS from baseline to study end

Item	Change baseline to study end
Reduced need for sleep	−63%
Sadness	−50%
Shifting emotions	−42%
Pessimism	−39%
Irritability	−38%
Anxiety	−37%
Slowed down	−34%
Excessively energetic	−20%

Table 3: Subjective report of subjects regarding characteristics of the app

Item	Score or percent use (1–7 scale with 1=to Disagree and 7=Agree)
Comfortable with tone/style of feedback	6.1
Helped me understand myself	6.1
Feedback in line with my emotional state	6.0
Became more aware of emotional shifts	5.9
Found advice helpful	5.8
Advice taught me something new	5.8
Using KIOS is beneficial	5.7
Helped me make better choices	5.4
Helped me with self-management	5.3
Helped me maintain positive mental health	5.3
Graphs helpful	5.1
Used positive behavior checklist	83%
Used audio feature	67%
Used downloadable report	58%

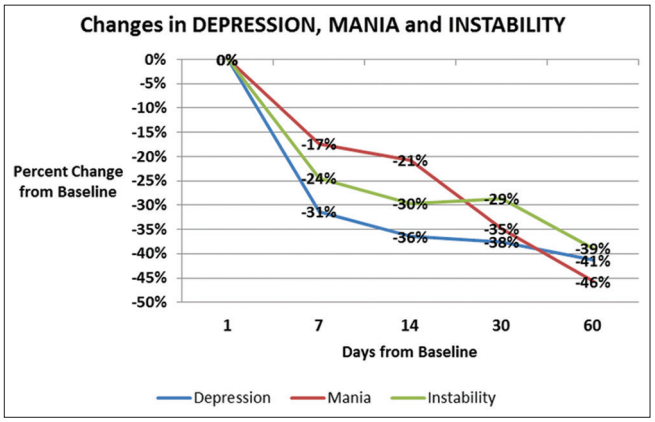

Figure 1: Changes in composite depression, mania, and general mood instability scores from study entry to study end

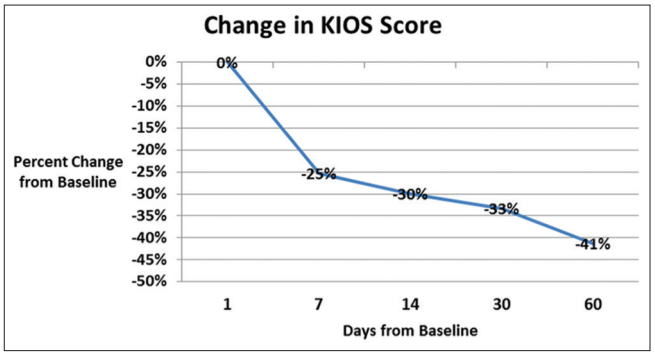

Figure 2: Composite KIOS score which combines depressive and manic symptoms and levels of mood instability

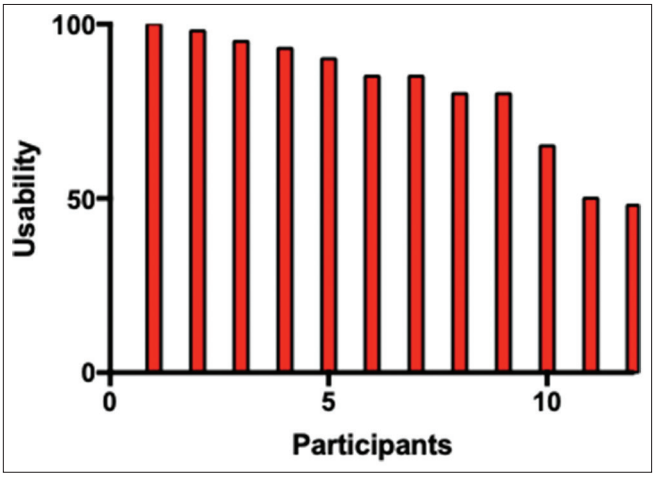

Figure 3: Usability score provided by all 12 participants on a 100-point scale

and really taught me things about myself personally), and two provided constructive feedback (Make everyday stress a factor to consider, not all issues are bipolar related; Overall good program but not as helpful for me as could have been). When asked how long they anticipate they would use KIOS, one said not at all after the study, three said for weeks, five said months, and 2 said years; one did not respond.

Discussion

The KIOS-Bipolar app is a tool that allows patients to self-monitor and self-manage their bipolar disorder while working with a healthcare provider. A previous randomized, comparison trial demonstrated that patients adhered to use of the KIOS-Bipolar app more avidly than the most commonly used self-monitoring app.[18] That study was performed in a psychiatric setting. The current open trial was performed to determine the utility of the app when the caregiver is a PCP. This is important since nearly a third of all bipolar patients are cared for by PCPs.[3,20] While this was not a randomized trial, all examined variables changed in a desirable fashion. The severity of both depressive and manic symptoms dropped significantly, as did the overall level of instability of the patients [Figures 1 and 2]. Overall patients felt the app was helpful and educational [Table 3].

It should be noted that these symptom monitoring scores and the level of improvement are comparable to those observed in the previous randomized trial.[18] This is notable given that this study was performed in a primary care setting while the previous one was performed in a specialty psychiatric clinic. This highlights the potential utility of self-monitoring technologies, in general, and KIOS-Bipolar, in particular, in the long-term management of bipolar disorder by PCPs.

The use of smart technology for self-management for chronic medical conditions such as diabetes[22] or hypertension[23] has been introduced and found to be helpful. Similarly, self-management may be also effective in BD.[24] Technologies for the management for bipolar illness are being developed,[25-27] and apps with similar goals as KIOS-Bipolar are being developed.[28,29] Self-monitoring has a longer history in BD than with other psychiatric conditions, that began with pen-and-paper technology[30] and proceeded smart technologies.[26,27] If self-monitoring is to be successful in self-management, it must be easy to use.[31]

Over 40% of primary care patients using the KIOS-Bipolar app gave it a usability score of ≥90, and the average was nearly 81 (on a 100-point scale). The app is currently available for patients to use and does not require a prescription (hhtps://Kiosbipolar.com).

There are clear limitations to this study. It was open, uncontrolled, brief, and utilized a small sample. However, it was designed to be a beta test of a previously studied app in a difficult population in the primary care setting. Despite the study's shortcomings, the preliminary results are quite promising. All clinical and usability variables measured in the study showed improvement. The incorporation of technology in nearly all aspects of medicine will only continue to grow. It is important that technologies used by patients are adequately studied.

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Conflicts of interest

There are no conflicts of interest.

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