STUDY PROTOCOL
https://doi.org/10.30773/pi.2024.0133
eISSN 1976-3026
OPEN ACCESS

Daily Self-Monitoring and Feedback of Circadian Rhythm Measures in Major Depression and Bipolar Disorder Using Wearable Devices and Smartphones–The Circadian Rhythm for Mood (CRM®) Trial Protocol: A Randomized Sham Controlled Double-Blind Trial

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The circadian rhythm for mood (CRM) is a digital therapeutic, which aims to prevent mood episode and improve clinical course in patients with major mood disorders. Developed on the circadian rhythm hypothesis of mood disorder, CRM predicts the impending risk of mood episode with its built-in algorithm, utilizing wearable devices data and daily self-reports, and provides personalized feedback. In a pilot study of the CRM, the users experienced less frequent and shorter duration of mood episodes than the non-users. To investigate the efficacy of the upgraded CRM, a double-blind, randomized, sham-controlled, parallel-group trial is designed. Patients aged between 19 and 70, diagnosed with bipolar I disorder, bipolar II disorder, or major depressive disorder, in a euthymic state for more than two months, can participate. During this 12-month trial, participants are assessed for episode recurrence every three months, and the efficacy of the CRM as a potential digital therapeutic is evaluated. Trial registration: ClinicalTrials.gov Identifier: NCT05400785.

Psychiatry Investig 2024;21(8):918-924

Keywords Mood disorders; Digital therapeutic; Circadian rhythms; Clinical trial.

INTRODUCTION

Major mood disorders, including major depressive disorder and bipolar disorder, are characterized by recurrent mood episodes and chronic subthreshold symptoms. Depression has a high recurrence rate of approximately 50%, with individuals experiencing 5−9 episodes over a lifetime. In bipolar disorder, over 90% of patients experience relapse, averaging 0.6 episodes annually.[1-4] With relapse and recurrence, the clinical course and prognosis of mood disorders worsen.[5,6] Therefore, predicting and preventing mood episodes is most important in mood disorder management.

Conventional treatment of mood disorders involves pharmaceutical and non-pharmaceutical treatment, including psychoeducation, cognitive behavior therapy, and psychotherapy. Despite medical advances, there is a great need for a paradigm shift to overcome the current limitations, considering that the success rate of antidepressant treatment is around 60% and that the prevalence of mood disorders is increasing.[7]

Understanding the pathophysiology of mood disorders with the circadian rhythm hypothesis and applying it to mood disorder management may open a new paradigm.[8-10] Circadian rhythm disturbances, such as changes in sleep-wake cycles, often precede mood episodes. Early detection of such disturbances may warrant personalized and timely treatment and

Received: April 25, 2024 **Revised:** June 3, 2024
Accepted: June 23, 2024

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even prevention of mood episodes through circadian rhythm stabilization. With advancements in digital health technology, it has become possible to assess circadian rhythm disturbances through objective, real-time data and offer tailored feedback to induce behavioral changes by recommending when to get bright light exposure.

Our team developed machine learning algorithms to predict depression and bipolar relapse using wearable devices and smartphones, conducted two prediction studies, developed a digital therapeutic called 'circadian rhythm for mood' (CRM), and conducted one pilot study of an intervention using CRM. CRM is a smartphone application with a built-in machine-learning algorithm that predicts the impending risk for mood episode and provides feedback for circadian rhythm stabilization. Data on activity, sleep, heart rate, and light exposure from wearable device and smartphone were used. The prediction studies showed that the algorithm predicted mood fluctuations three days in advance with approximately 90%−95% accuracy when compared to clinician-assessed mood episodes every three months.[11,12] This finding indicates that passively collected digital data and circadian rhythm parameters provide valid clinical information for mood disorders. In the past, we conducted small-sample, open-label, controlled intervention pilot studies on the CRM app. Seventy-three patients with major mood disorders were divided into CRM (n=14) and non-CRM (n=59) groups, with 10 and 33 subjects, respectively, completing the study. Over 12 months, both groups received similar treatments; however, only the CRM group received feedback and alerts based on their activity data. Mood episodes were assessed every three months. As a result, the CRM group experienced significantly fewer and shorter depressive and manic episodes compared to the non-CRM group, along with positive changes in health behaviors and device adherence.[13]

We designed a double-blind, randomized, sham-controlled, parallel-group study to evaluate the efficacy of CRM on recurrence rate and duration of mood episodes in patients with bipolar I disorder, bipolar II disorder, and major depressive disorder. In this 12-month study, clinician assessments including mood episode recurrence, self-reported demographic information, medical and psychiatric history, and questionnaires are conducted at three-month intervals. Additionally, study participants use wearable devices and record daily mood data via eMoodChart of CRM.

DESIGN AND METHODS

Purposes

The primary objective is to evaluate the efficacy of the CRM in reducing the recurrence rate and duration of mood episodes. A comparison will be made between recurrence rates and duration of overall mood episodes across active and sham groups. Secondary objectives include: 1) assessing changes in overall clinical severity and subjective quality of life over the duration of CRM usage; 2) evaluating adherence to the utilization of the CRM and wearable device to analyze associations with the primary outcomes of the study; and 3) examining the user experience of the CRM to ascertain associations with primary outcomes and to provide insights for future enhancements to the CRM.

Participants

Inclusion criteria include participants who are: 19−70 years old; diagnosed with bipolar I disorder, bipolar II disorder, or major depressive disorder according to Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition (DSM-5) criteria; in a euthymic state for over two months at recruitment; Android smartphone users capable of installing and executing the CRM; and willing to wear a Fitbit continuously, synchronize, and backup data regularly.

Participants are excluded if they have not experienced a major depressive, manic, or hypomanic episode in the past two years; difficulties specifying mood episodes or evaluating symptoms independently due to personality traits (borderline personality trait, cyclothymic temperament, etc.); degenerative neurological disorders (Parkinson's disease, dementia, Huntington's disease, etc.); neurodevelopment disorders (intellectual disorder, autism spectrum disorder, Down syndrome, etc.); epilepsy; severe traumatic brain damage; stroke; or other brain neurological disorder; involuntarily detained due to psychiatric or medical conditions; and difficulties understanding and giving informed consent to the study.

Study design

An overview of the study procedure is presented in Figure 1. The study evaluates the efficacy of the CRM in preventing mood episodes. Participants use the CRM for a total of 12 months, with in-person assessments conducted at baseline and every three-month interval. Initial assessments include sociodemographic information, psychiatric diagnostic instruments, and clinical information. Subsequent assessments focus on mood episode recurrence and clinical information, correlating and establishing reliability with data collected in the CRM. At the end of the study, participants are asked to fill out a survey for their input to enhance and refine the technology of CRM.

Participants wear a wearable device for a continuous 24-hour and record the eMoodChart daily on the CRM. The eMoodChart is an ecological momentary assessment with items asking about mood state (-3 to +3), energy level (-3 to +3), anxiety (0−3), irritability (0−3), and alcohol drinking (yes or no).

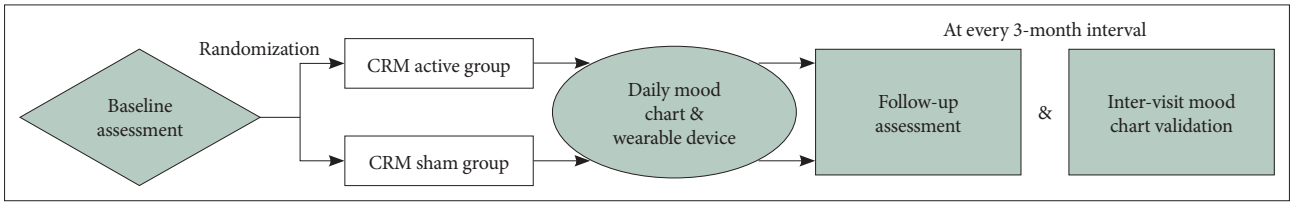

Figure 1. The overall design of CRM study, CRM, circadian rhythm for mood.

The accumulated data from wearable device and eMood-Chart are analyzed by the machine-learning algorithm of the CRM system to evaluate the users' circadian rhythm. The CRM system then generates predictions about users' future mood state and sends individualized feedback. The app delivers lifestyle analysis, future mood predictions, and instructions to the users through the 'Life Report' and notifications. Through randomization at the enrollment of the study, study participants are assigned to either the CRM active or the CRM sham group. The CRM active group receives individualized lifestyle analysis and feedbacks; on the contrary, the CRM sham group is provided with information powered by a dummy algorithm. The sham CRM is visually indistinguishable from the active CRM but is designed to minimize behavioral changes in users.

This double-blind, randomized, sham-controlled, multicenter study collects data from five sites in South Korea: Korea University Anam Hospital, Korea University Guro Hospital, Korea University Ansan Hospital, Inje University Ilsan Paik Hospital, and Pusan National University Hospital. Informed consent is obtained from all participants prior to the study. The Institutional Review Boards of all five participating hospitals reviewed and approved this study (2022AN0165), and the study is registered under the ClinicalTrials.gov identifier NCT05400785.

Assessments

Assessments are conducted at the baseline and at every three-month interval. Initially, screening evaluations for inclusion and exclusion criteria for the CRM study and baseline assessment are performed. Following screening, clinicians are required to confirm and record participants' most recent diagnoses using the DSM-5[14] and at each subsequent visit. After enrollment with CRM installation and Fitbit wear, participants have follow-up assessments every three months. Assessments are composed of sections completed by clinicians, investigators, and participants (Table 1).

Demographic information and clinical data

The demographic and clinical information collected at the baseline assessment are: age, sex, height, body weight, socioeconomic status, average monthly income, education year, marital status, occupational status, medical service usage patterns and average monthly medical expenses, list and dosage of prescribed medications for psychiatric condition, treatment compliance in percentage, and sleep pattern (bed-in time, sleep latency time, wake-up time, average monthly time-in-bed, and nap). Follow-up assessments inquire about medical service usage patterns, average monthly medical expenses, list and dosage of prescribed medications for psychiatric condition, treatment compliance percentage, and sleep pattern over the previous three months.

Psychiatric assessments by clinicians

The Korean version of the Mini-International Neuropsychiatric Interview is used for psychiatric diagnosis by trained clinical psychiatrists at the baseline assessment.[15] Clinicians also inquire about psychiatric history, including the type of first mood episode, the number of previous depressive, manic, and hypomanic episodes, the number of previous psychiatric admissions, suicidal attempts, non-suicidal self-mutilation, psychiatric family history, medical history, and retrospective Assessment of the Lithium Response Phenotype Scale for lithium treatment response.[16,17] Clinicians also complete questionnaires: suicide intent scale,[18] Korean versions of Montgomery-Åsberg Depression Rating Scale[19] and Young Mania Rating Scale,[20] and Clinical Global Impression-Bipolar.[21] At follow-up assessments, clinicians evaluate mood episode recurrence during the past three months. They also collect information on psychiatric admission, international travel, suicidal attempt, and non-suicidal self-mutilation for the previous three months, in addition to performing the same scales done at the baseline assessment.

Self-report psychiatric assessments by patients

The study participants perform self-report assessments at baseline and follow-up visits. The assessments are selected for their relevance to mood disorders. At baseline, a total of 15 assessments are utilized: Korean Version of Drug Attitude Inventory-10,[22] Korean Version of Childhood Trauma Questionnaire,[23] Biological Rhythms Interview of Assessment in Neuropsychiatry,[24] Quick Inventory of Depressive Symptomatology.[25] Beck Anxiety Inventory,[26] Hypomania Symptom Checklist-32,[27] Mood Disorder Questionnaire,[28] Scale for Sui-

Table 1. Assessment items of the CRM study

Assessment items	Screening/ baseline	Visit 1 Month 3 ±2 weeks	Visit 2 Month 6 ±2 weeks	Visit 3 Month 9 ±2 weeks	Visit 4 Month 12 ±2 weeks
Demographic information and clinical data					
Demographic and socioeconomic status	√				
Recent medical usage patterns and monthly average medical expenses	√	√	√	√	√
History of psychiatric medication and drug compliance	√	√	√	√	√
Sleep pattern	√	√	√	√	√
Psychiatric assessments by clinicians					
MINI	√				
Psychiatric history	√				
Most recent diagnosis	√				
First-onset episode and total episodes	√				
Familial psychiatric history	√				
ALDA scale	√				
Medical history	√	√	√	√	√
SIS	√	√	√	√	√
K-MADRS	√	√	√	√	√
YMRS	√	√	√	√	√
CGI-BP	√	√	√	√	√
Mood episode evaluation		√	√	√	√
Basic psychiatric information		√	√	√	√
Self-report psychiatric assessments by patients					
KDAI-10	√				
K-CTQ	√				
BRIAN	√	√	√	√	√
QIDS	√	√	√	√	√
BAI	√	√	√	√	√
HCL-32	√	√	√	√	√
MDQ	√	√	√	√	√
SSI-Beck	√	√	√	√	√
BHOL	√	√	√	√	√
BIS	√	√	√	√	√
CSM	√	√	√	√	√
SPAQ	√	√	√	√	√
WHOQOL-BREF	√	√	√	√	√
IPAQ-SF	√	√	√	√	√
LES	√	√	√	√	√

CRM, circadian rhythms for mood; MINI, Mini-International Neuropsychiatric Interview; ALDA scale, Retrospective Assessment of the Lithium Response Phenotype Scale; SIS, Suicide Intent Scale; K-MADRS, Korean versions of Montgomery-Åsberg Depression Rating Scale; YMRS, Young Mania Rating Scale; CGI-BP, Clinical Global Impression-Bipolar; KDAI-10, Korean version of Drug Attitude Inventory-10; K-CTQ, Korean version of the Childhood Trauma Questionnaire; BRIAN, Biological Rhythms Interview of Assessment in Neuropsychiatry; QIDS, Quick Inventory of Depressive Symptomatology; BAI, Beck Anxiety Inventory; HCL-32, Hypomania Symptom Checklist-3; MDQ, Mood Disorder Questionnaire; SSI-Beck, Scale for Suicide Ideation-Beck; BHOL, Beck Hopelessness Scale; BIS, Barratt Impulsiveness Scale; CSM, Composite Scale of Morningness; SPAQ, Seasonal Pattern Assessment Questionnaire; WHOQOL, Korean Version of WHO Quality of Life Scale abbreviated version; IPAQ-SF, International Physical Activity Questionnaire-Short Form; LES, Life Experiences Survey

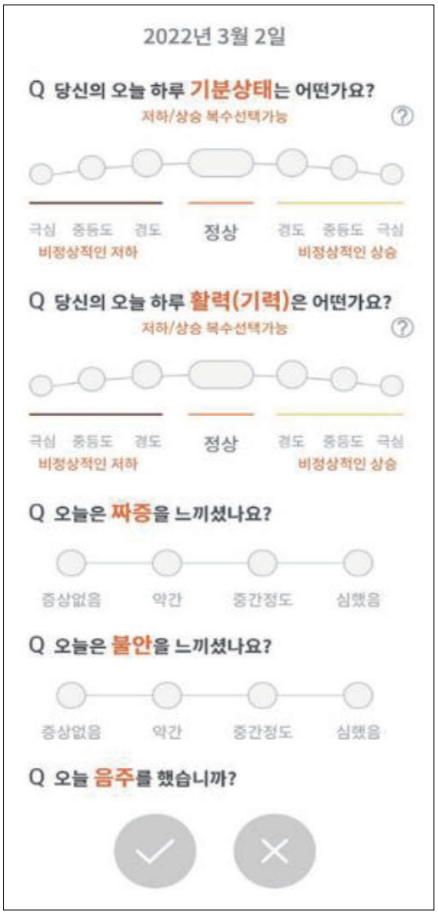

Figure 2. Screenshot of the eMoodChart of the circadian rhythm for mood.

cide Ideation-Beck,[29] Beck Hopelessness Scale,[30] Barratt Impulsiveness Scale,[31] Composite Scale of Morningness,[32] Seasonal Pattern Assessment Questionnaire,[33] Korean Version of WHO Quality of Life Scale abbreviated version,[34] International Physical Activity Questionnaire-Short Form,[35] and Life Experiences Survey.[36] Follow-up assessments consist of the same questionnaires except for the Korean Version of Drug Attitude Inventory-10 and Korean Version of Childhood Trauma Questionnaire.

CRM

The CRM is available for download on the Android OS app store and installed on participants' smartphones upon study enrollment. Participants record their mood state, energy state, irritability, and anxiety daily on eMoodChart (Figure 2). Daily reminders prompt completion of eMoodChart if it is not completed. The viewing pages offer information on the overall life rhythm score, life rhythm scores of the four domains (activity, sleep, light exposure, and circadian rhythm), and mood state prediction in the next three days using a face icon. Additional pages allow participants to view the recordings of their recent overall life rhythm scores and impending risk for mood episodes (Figure 3).

Active vs. Sham

The use of a sham control app. in this study is different from the previous digital therapeutic trials. On the surface, active and sham appear entirely identical. However, the key distinc-

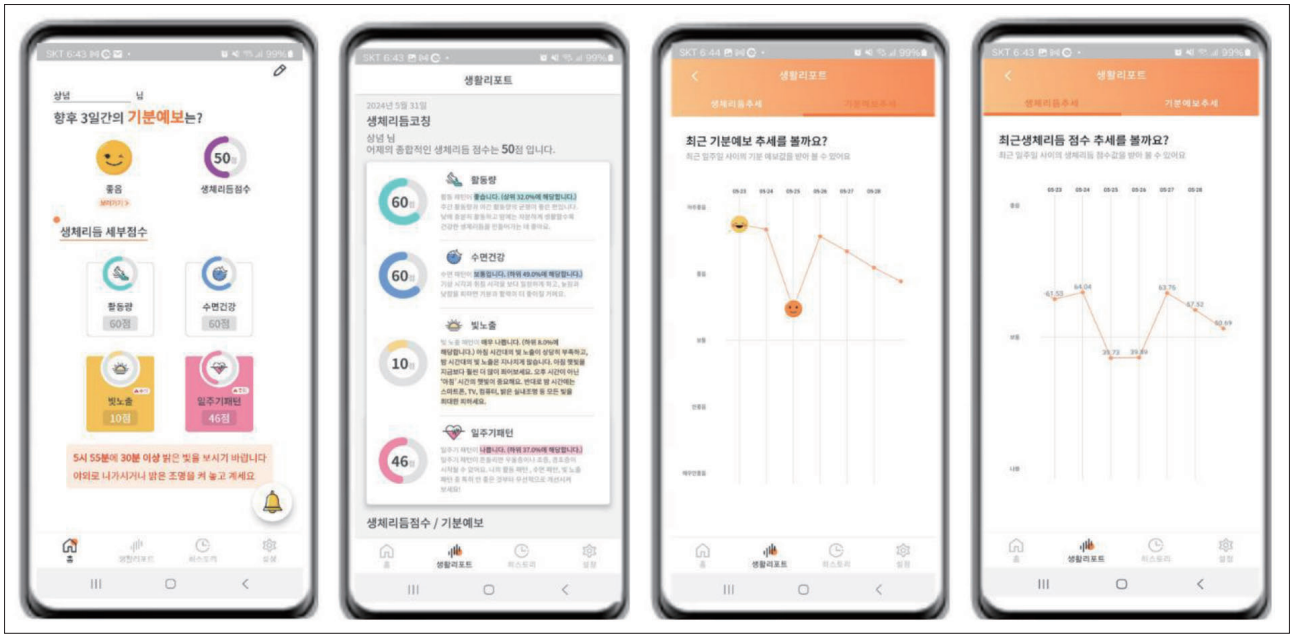

Figure 3. Screenshots of the view pages of the circadian rhythm for mood showing (left to right): page with mood state prediction for the next three days with overall life rhythm score and sub-scores for the four domains of activity, sleep, light exposure, and circadian rhythm; page with more details on each domain with assessment and recommendation; page showing the results of mood state prediction for next three days in the past few days; and page showing the results of overall life rhythm score in the past few days.

tion lies in the fact that active aims to induce improvements in lifestyle habits and enhance solid circadian rhythm based on information obtained from wearable devices and smartphone light sensors, whereas sham provides false feedback to maintain current lifestyle habits and avoid inducing changes in lifestyle habits. To achieve this, we set the most important feature of the CRM, the recommended wake-up and light exposure time, to 'DLMO (dim-light melatonin onset) estimated time+13 hrs' (in Active, the wake-up and light exposure recommendation is 'DLMO estimation time+9.5 hrs'). This setting of sham should have little impact on circadian rhythms. In addition, the feedback provided in the sham group is designed to be randomized with scores ranging from fair to good (60–90) to ensure that the CRM does not encourage lifestyle changes.

DATA MANAGEMENT AND ANALYSES

Data management

All assessments collected for the study are electronic case record forms built with the Research Electronic Data Capture (REDCap), a secure web application.[37,38] Tablets are utilized to collect data, managed through REDCap to ensure data confidentiality. Access is limited to authorized researchers.

Statistical analyses

A descriptive analysis of demographic information and baseline clinical characteristics will be performed in the study. This analysis will include presenting the number of subjects, mean, standard deviation, minimum and maximum values for continuous data, and frequencies and percentages for categorical data. Differences between groups will be analyzed by independent two-sample t-tests (active vs. sham) and analysis of variance for continuous data, and chi-square tests for categorical data. If factors with significant differences between groups are identified, further analyses (e.g., post-hoc analysis) will be performed accordingly.

CONCLUSION

The paradigm of management in psychiatry is shifting with the rise of digital therapeutics. Mood disorder is a major psychiatric illness that is prevalent and causes a significant decline in social, academic, or occupational function and quality of life. The circadian rhythm hypothesis suggests circadian rhythm disturbances precede mood episodes. Wearable devices and smartphone applications can detect these disturbances, allowing for the prediction and prevention of mood recurrences. A smartphone application enables mood disorder patients to self-monitor and adjust their lifestyles based on personalized feedback provided by the application. Prevention of mood episode recurrences is one of the most important treatment goals for mood disorder patients; therefore, introducing a digital therapeutic that serves as a means for circadian rhythm stabilization will greatly benefit mood disorder patients. In this study, we will investigate the therapeutic effect of the upgraded CRM as a non-prescription digital therapeutic in preventing mood episodes and assess the user experience of the application. Our goal is to expand treatment options for mood disorder patients and empower them to proactively monitor and manage their mood symptoms.

Availability of Data and Material

Data sharing not applicable to this article as no datasets were generated or analyzed during the study.

Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

Author Contributions

Conceptualization: Heon-Jeong Lee, Leen Kim. Methodology: Heon-Jeong Lee, Chul-Hyun Cho, Taek Lee, Jung-Been Lee, Sehyun Jeon. Funding acquisition: Heon-Jeong Lee. Investigation: Ji Won Yeom, Yeaseul Yoon, Ju Yeon Seo. Writing—original draft: Ji Won Yeom, Yeaseul Yoon. Writing—review & editing: Heon-Jeong Lee.

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Funding Statement

This study was supported by grant number HI22C147200 from the Ministry of Health & Welfare and the technology development program (S3200157) funded by the Ministry of SMEs and Startups (MSS, Korea).

Acknowledgments

None

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