STUDY PROTOCOL
https://doi.org/10.4306/pi.2017.14.1.100

Print ISSN 1738-3684 / On-line ISSN 1976-3026
OPEN ACCESS

Design and Methods of the Mood Disorder Cohort Research Consortium (MDCRC) Study

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The Mood Disorder Cohort Research Consortium (MDCRC) study is designed as a naturalistic observational prospective cohort study for early-onset mood disorders (major depressive disorders, bipolar disorders type 1 and 2) in South Korea. The study subjects consist of two populations: 1) patients with mood disorders under 25 years old and 2) patients with mood disorders within 2 years of treatment under 35 years old. After successful screening, the subjects are evaluated using baseline assessments and serial follow-up assessments at 3-month intervals. Between the follow-up assessments, subjects are dictated to check their own daily mood status before bedtime using the eMood chart application or a paper mood diary. At the regular visits every 3 months, inter-visit assessments are evaluated based on daily mood charts and interviews with patients. In addition to the daily mood chart, sleep quality, inter-visit major and minor mood episodes, stressful life events, and medical usage pattern with medical expenses are also assessed. Genomic DNA from blood is obtained for genomic analyses. From the MDCRC study, the clinical course, prognosis, and related factors of early-onset mood disorders can be clarified. The MDCRC is also able to facilitate translational research for mood disorders and provide a resource for the convergence study of mood disorders.

Psychiatry Investig 2017;14(1):100-106

Key Words Cohort study, Early mood disorders, Bipolar disorder, Major depressive disorder, MDCRC.

INTRODUCTION

Mood disorders, such as major depressive disorders and bipolar disorders, are common mental illnesses with a long-time course.[1,2] Patients with mood disorders usually experience impairments in important social roles and comorbidities with medical illnesses in addition to mood-related symptoms.[2] Functional impairment or decrements in health-related quality of life associated with mood disorders were reported to be greater than those associated with chronic medical conditions such as diabetes, arthritis, and chronic cardiac or pulmonary disease.[3-5] Moreover, suicidal behavior and commitment is a severe social problem, and it is more prevalent in mood disorders.[6,7]

Kessler et al.[8] reported mood disorder age of onset curves showing consistently low prevalence until the early teens, a rough increase through late middle age, and a declining increase thereafter. Generally, the median age of onset for mood disorders is reported as a wide range (25–45 years old).[8] Younger onset age is known to be one of the most replicated risk factors for the switch from depression to (hypo)mania or mixed states.[9,10] It is crucial to investigate the clinical features and prognosis of early-onset mood disorders in order to understand the pathophysiology and course of mood disorders in

Received: June 18, 2016 **Revised:** July 29, 2016
Accepted: August 4, 2016 **Available online:** December 27, 2016

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general, including predicting factors of recurrence or switching, environmental factors, circadian rhythm characteristics, and biological mechanisms.

Most assessments in mood disorder research have included checking clinical symptoms at a series of scheduled visits. However, there may be various events and mood changes during inter-visit periods, and clinicians and even patients could easily miss what happened during these inter-visit periods. Many researchers have tried to compensate for this possibility by using tools, such as a diary form.[11-13] Recently, it has become much more possible to assess the daily status of mood disorder patients with the development of information communication technology (ICT).[14-17]

We designed and are performing a longitudinal observational prospective cohort study for early-onset mood disorder patients called the Mood Disorder Cohort Research Consortium (MDCRC) Study. The MDCRC Study is aimed to evaluate demographic information, medical and psychiatric history, clinical features and courses, and prognosis of mood disorders by assessing patients every 3 months as well as during inter-visit periods using the daily eMood chart smart phone application.

DESIGN AND METHODS

Purposes

The main purpose of the MDCRC study is to investigate demographic information, medical and psychiatric history, clinical characteristics, course, and prognosis, as well as assess the risk factors or preventive factors associated with relapse or recovery or diagnostic conversion from unipolar depressive disorder to bipolar disorder targeting early-onset mood disorders. Additionally, the MDCRC study aims to facilitate translational research for mood disorders and to provide a resource for the study of mood disorders, such as bridging translational research and ICT convergence research on mood disorders by utilizing unique resources. Furthermore, the additional purpose of the MDCRC is to present a new methodology of mood disorders research. By complementing the shortcomings of the various mood disorders studies that have been conducted so far, our team aims to develop and perform specific research methods that reflect the clinical aspects of mood disorders.

Cohort populations

The MDCRC study recruits mood disorder patients who fulfill the criteria of the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) for major depressive disorder, bipolar I disorder, or bipolar II disorder.[18] Generally, mood disorder patients do not receive treatment from the beginning of major mood symptoms for several reasons.[19-22] In fact, mood disorder patients initially visit psychiatric clinics and are diagnosed after a considerable period of time from the initial experience of major mood symptoms.[19-22] Early mood disorder is defined as follows: 1) under 25 years old with mood disorder; or 2) under 35 years old with mood disorder within 2 years of treatment. We exclude patients with intellectual disability or organic brain injury, and/or difficulty reading and understanding the Korean language.

Study design

The assessment schedule consists of the baseline assessment, inter-visit assessment, and follow-up assessment. The overall configuration of the MDCRC study is depicted in Table 1. The follow-up assessment is divided into formal assessment and telephone-based assessment according to the evaluation methods and into scheduled visit assessment and unscheduled visit assessment depending on the time of evaluation. Tele-

Table 1. The overall configuration of the MDCRC study

	Contents	Time	Raters
Baseline assessment	Baseline evaluation	Baseline	Clinicians Research staff Patients
	Blood sampling	Baseline	Research staff
Inter-visit assessments	Daily mood diary	Every routine day during inter-visit period	Patients
	Inter-visit mood chart validation	Follow-up visit	Clinicians
	Inter-visit mood episode evaluation	Follow-up visit	Clinicians
Follow-up assessment	Follow-up evaluation	Follow-up visit	Clinicians Research staff Patients
	Telephone-based follow-up evaluation	Follow-up visit	Research staff

MDCRC: Mood Disorder Cohort Research Consortium

phone-based assessment could be used only for limited cases when patients cannot visit the hospital for acceptable reasons, and it is contrived to reduce drop-out from the study. Scheduled visits for follow-up assessments are performed every 12 weeks from the baseline assessment. For inter-visit assessments, all the subjects are dictated to check a daily mood chart using the eMood chart application for smartphones or personal computers. If it is not applicable, the eMood chart is replaced by a paper mood diary. The daily mood chart is an important component of the inter-visit assessment. Patients are provided a daily mood chart that asks for mood state (-3 to +3), energy level (-3 to +3), anxiety (0−3), irritability (0−3), drinking (yes or no), prescription medication use (yes or no), total sleep time (hours), weight (once every two weeks), and menstruation (only for women). A trained psychiatrist reviews the records of the daily mood charts at every visit at an outpatient clinic or at the follow-up assessments. By reviewing daily mood charts and interviewing patients, the psychiatrist validates the daily mood chart and sometimes can modify the mood chart according to the judgment of the clinician. This process is called "inter-visit mood chart validation." After the inter-visit mood chart validation process, a psychiatrist determines whether there have been possibilities of major or minor mood episodes during the inter-visit period. When a major or minor mood episode is suspected from the daily mood chart validation, investigators proceed to the next step called "inter-visit mood episode evaluation." At the inter-visit mood episode evaluation step, clinicians ask patients about mood episodes according to DSM-5 criteria and establish a most recent diagnosis. If a major or minor mood episode is not suspected from the inter-visit mood chart validation, investigators skip the mood episode evaluation step and finish the follow-up assessment. Overall design of the MDCRC study is presented in Figure 1.

The MDCRC study started in September 2014 and will be sustained for at least 5 years. Since mood disorders have chronic and various clinical courses, many diagnosed cases of unipolar depression are known to change to bipolar disorder. It is very important to follow-up for long-term periods in the course of mood disorders, and we want to follow-up as long as possible.

Assessments

Various assessments are performed at each visit starting from the baseline assessment. At first, screening evaluations for inclusion and exclusion criteria for the MDCRC Study are performed. After successful screening, at every visit thereafter, clinicians have to check and write down patients' most recent diagnosis according to the DSM-5.[18] Assessment is composed of demographic and clinical data, psychiatric assessment by investigators and patients, and biological assessment, which is the same as mentioned below (Table 2).

Demographic and clinical data

The demographic data at baseline assessment consists of age, gender, height, weight, waist circumstance, handedness, and socioeconomic status, such as the average monthly income, education level, marital status with children, and kinds of jobs.

The sleep pattern was assessed by asking the sleep onset time, wake-up time, sleep latency time, total sleep time, and nap time. Almost all questions asked are divided by weekdays and weekends.

Medication history is precious information to understand patients with mood disorders. However, it is very difficult to investigate prescribed past medication history for treatment of mood disorders. We decided to investigate only whether the patients have been prescribed lithium for treatment instead of conducting a full investigation of medication history. If the patients have experiences of lithium medication, the clinician checks the ALDA scale for evaluating the responsiveness of lithium treatment.[23,24] All psychiatric medication is recorded from the baseline assessment and at every follow-up assessment by checking the patients' medication compliance, which is the percentage of real medicated drugs among pre-

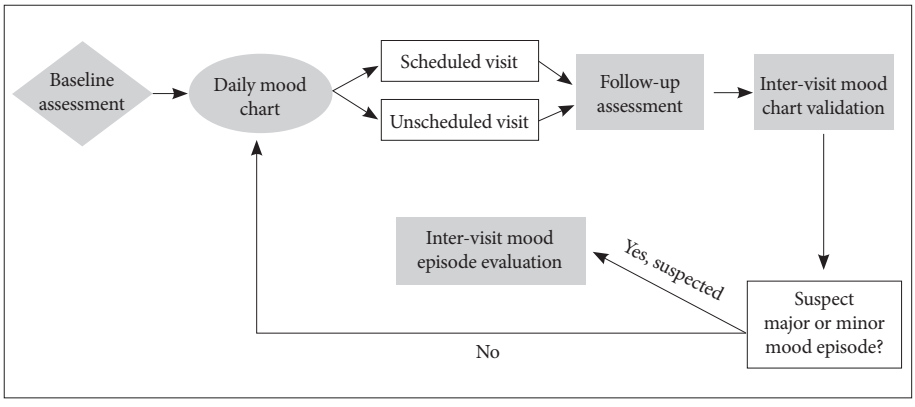

Figure 1. The overall design of the MDCRC study. MDCRC: Mood Disorder Cohort Research Consortium.

scribed drugs.

We investigate whether the patients have history of suicide attempts. If there has been history of suicide attempts, then patients are asked the age of the first attempted suicidal event and the number of suicidal attempts with or without mood episodes. Suicidal history is also assessed at every follow-up visit for investigation of inter-visit suicidal events.

Familial psychiatric history is assessed by asking for psychiatric treatment history, such as bipolar disorder, depressive disorder, alcohol and substance use disorders, anxiety disorders, schizophrenic spectrum disorders, and other psychiatric problems, including suicide.

The medical and surgical history is asked for assessment of past and current comorbidities. Moreover, average monthly cost of treatment is assessed for psychiatric, medical, dental, and oriental medicinal managements as well as medical usage patterns at every assessment. Smoking and alcohol history including duration and quantity of the uses is also checked for all patients at every assessment. Evaluation of menopause state is performed only for female participants.

Psychiatric assessment by investigators

The Korean version of the Mini-International Neuropsychiatric Interview (MINI) was used for psychiatric diagnosis by clinicians who are expert in psychiatry at the baseline assessment.[25] Patients with mood disorders often suffer from comorbid psychiatric symptoms. Psychiatric comorbidity was assessed by the same clinicians at every visit from the baseline assessment to catch newly developed psychiatric problems.

Routine mood symptom scales including the Montgom-

Table 2. Assessment items of the MDCRC study

Assessment items	Baseline assessment	Follow-up assessment
Inclusion and exclusion criteria	√	
Most recent diagnosis	√	√
Demographic and Socioeconomic state	√	
Information on first-onset episode and total episodes	√	
Sleep pattern	√	√
Medical history	√	√
Recent medical usage patterns and monthly average medical expenses	√	√
MINI International Neuropsychiatric Interview	√	
Psychiatric co-morbidity	√	√
Suicidal history	√	√
History of psychiatric medication and drug compliance	√	√
ALDA questionnaire for Lithium treatment response	√	
Familial psychiatric history	√	
Montgomery-Åsberg Depression Rating Scale	√	√
Young Mania Rating Scale	√	√
Clinical Global Impression-Bipolar	√	√
Biological Rhythms Interview of Assessment in Neuropsychiatry	√	√
Quick Inventory of Depressive Symptomatology	√	√
Hypomania Symptom Checklist-32	√	√
Mood Disorder Questionnaire	√	√
Barratt Impulsiveness Scale	√	√
Composite Scale of Morningness	√	√
Korean Version of Drug Attitude Inventory-10	√	
Seasonal Pattern Assessment Questionnaire	√	√
Korean version of WHO Quality of Life Scale abbreviated version	√	√
The International Physical Activity Questionnaire-Short Form	√	√
Life Experiences Survey	√	√
Biological assessment (Blood sampling)	√	

MDCRC: Mood Disorder Cohort Research Consortium

ery-Åsberg Depression Rating Scale (MADRS) for depressive symptoms[26] and the Young Mania Rating Scale (YMRS) for manic symptoms[27] are applied. The Biological Rhythms Interview of Assessment in Neuropsychiatry (BRIAN) is checked to evaluate circadian rhythm tendencies in participants.[28] The Clinical Global Impression-Bipolar (CGI-BP) Scale is also investigated by clinicians at every assessment.[29]

Psychiatric assessment by patients (self-report)

There are various self-report scales for evaluating patients' psychiatric state and history. We selected the self-report forms and subjective scales that are considered to be important for the study of patients with mood disorders. The Quick Inventory of Depressive Symptomatology,[30] Hypomania Symptom Checklist-32,[31] and Mood Disorder Questionnaire[32] are provided to patients for assessing mood symptoms such as depression, anxiety, hypomania, or bipolarity phenotypes. The Barratt Impulsiveness Scale[33] is applied for evaluating other important states closely related to mood problems. The Korean Version of Drug Attitude Inventory-10 is checked once for evaluating patient's compliance with biological treatment at baseline assessment.[34] For evaluating patients' seasonality and chronotype, the Seasonal Pattern Assessment Questionnaire[35] and Composite Scale of Morningness[36] are provided at every visit. The Korean version of WHO Quality of Life Scale abbreviated version is asked for subjective perception of quality of life in patients with mood disorders.[37] General physical activity is another important aspect of mood disorders, so we apply The International Physical Activity Questionnaire-Short Form.[38] Since various events occur in routine life and perceived stress from the events could affect the prognosis of mood disorders, the Life Experiences Survey is checked by each patient at every assessment.[39]

Blood sample collection

Blood sample collection from all participants is performed once at the baseline enrollment of the study. Blood samples (10 mL) are collected into ethylenediaminetetraacetic acid (EDTA) bottles and stored in a -30°C freezer. They will be used for genomic analyses or other biological analyses.

Database management and analyses

Clinical data are registered electronically via an electronic case report form based on the Internet-based Clinical Research and Trial Management System (iCReaT) established by the Centers for Disease Control and Prevention, Ministry of Health and Welfare, Republic of Korea (iCReaT, Study No. C150010). The data will be encrypted, and it will have limited access that is managed by iCReaT data managers.

There could be various objects for analysis from the MDCRC Study. We will use various statistical analysis methods depending on the characteristics of data and each hypothesis. For the analysis of demographic, clinical features, prognosis (including predictors and medical usage between different clinical groups of mood disorders), we will use paired t-test, logistic regression analysis, repeated measures ANOVA, Cox proportional hazard regression, and so on. For the analysis of longitudinal data of clinical symptom changes, mixed linear models taking into account the correlation between the different assessment variables of mood disorder patients in the course of the cohort study assessment schedule will be used.

Collaboration with a study using wearable activity trackers

Because one of the study's purposes is to facilitate translational research for mood disorders, the MDCRC study has a collaboration with a circadian rhythm study of mood disorders using a wearable activity tracker. The study participants also participate in the wearable activity tracker study when they want to join. Various variables such as activity, sleep, and heart rate will be obtained from wearable activity tracker. The MDCRC study is aimed to have further collaborations with translational research such as ICT convergence research on mood disorders.

CONCLUSION

Until now, various cohort studies of mood disorders have been conducted to investigate clinical and biological information. Each cohort study of mood disorders had their own purposes and methods, such as naturalistic cohort studies with clinical populations or with community populations and cohort studies with clinical populations designed for clinical trials.[40] Because mood disorders are characterized as long-lasting with repeating recurrence and impairment of social functioning,[1,2] it is still necessary to perform cohort studies for mood disorders with various purposes and methods. Based on the review of previously performed cohort studies for mood disorders, we designed and are performing a cohort study focusing on early mood disorders to investigate demographic information, medical and psychiatric clinical features, medical usage pattern and medical expenses, and prognosis, including diagnostic conversion from unipolar to bipolar disorder of patients by assessments at scheduled visits as well as during inter-visit periods. From the design and methods of the MDCRC study, it is expected to overcome some limitations of previously performed cohort studies for mood disorders, through daily mood chart evaluation for assessment of inter-visit periods, unscheduled visit to catch up aggravation of the symptoms, and using ICT methods. We look forward to getting an

enormous amount of clinical and biological information concerning mood disorders, to help translational research through the resource of our cohort study, and to present a research methodology reflecting the characteristics of mood disorders.

Acknowledgments

This study was supported by the Korea Health 21 R&D Project funded by the Ministry of Health & Welfare, Republic of Korea (HM14C2606).

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