TITLE OF RESEARCH: Development and Testing of a Behavioral Activation Mobile Therapy for Elevated Depressive Symptoms (RCT)

NCT04463914

Principal Investigator: Jennifer Dahne, Ph.D.

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

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Concise Summary

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this research study is to evaluate a mobile application (app) for depression treatment called "Moodivate". Moodivate was developed by our research team to assist with the treatment of depressed mood within primary care.

If you agree to participate, you will be randomly assigned to either download the mobile app, "Moodivate", or not. Approximately 400 participants will receive the mobile app and the remaining 200 will not. An additional ten participants will be enrolled at the beginning of the study and will all be assigned to receive the Moodivate mobile app. These initial participants will be asked to provide feedback regarding their experiences using the mobile app in order to improve Moodivate for future participants. The primary care providers of half of the participants (i.e., 200) who receive Moodivate will be granted access to a provider portal within the Electronic Health Record (EHR) through which they can review your utilization of Moodivate.

You will be asked to complete electronic questionnaire measures throughout the study period. Questionnaires will assess symptoms of depression as well as your experiences using Moodivate. In addition to these electronic questionnaires, if you are provided with Moodivate, our study team will collect data regarding your use of Moodivate. Participation in this study will take about 12 weeks, beginning today.

Participation in this study may help in the treatment of future individuals with symptoms of depression. The greatest risks of this study include frustration, worsening of emotional distress, data breach, and/or loss of confidentiality. Alternative treatments include contacting your primary care provider to discuss other available treatments for depressed mood.

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this consent document carefully and take your time deciding whether you would like to participate. The purpose of this study is to evaluate a mobile application (app) for depression treatment called "Moodivate." Moodivate was developed by Dr. Dahne and her research team to assist with the treatment of depressed mood within primary care. Moodivate focuses on tracking daily activities, recording daily mood, and identifying new activities to complete that may help improve mood. Dr. Dahne and her research team plan to commercialize Moodivate in the future. As such, Dr. Dahne has commercial interest in the development and evaluation of Moodivate. You are being asked to participate in this study because you were identified during your initial screening as having elevated symptoms of depression. The investigator in charge of this study is Dr. Jennifer Dahne. The study is sponsored by a grant from the National Institutes of Health. Portions of Dr. Dahne's and her research team's salaries may be paid by this grant. The study is being done at one site. Approximately 695 people will take part in this phase of the study, all at the Medical University of South Carolina (MUSC).

B. PROCEDURES

If you agree to participate in this project, the following will happen:

1. Agreeing to be in this study will allow the research team access to information you provided during your screening to be used for research purposes.
2. If you are one of the first ten participants enrolled in the study, you will be enrolled in the experimental (i.e., Moodivate) condition and will be asked to provide feedback to the research team as you use the app. If you are enrolled as part of this group, you will be informed by the research staff prior to consent. All other study procedures outlined below will be the same as if you were randomly assigned to the experimental condition.
3. You will be randomly assigned into one of three groups. You will not have the opportunity to choose which group you are in. You have a 1 in 3 chance of being assigned to each group.
4. If you are randomly assigned to Group A (the *control condition*), you will be provided with educational material about mood management and it will be suggested that you discuss any questions about mood management with your primary care provider. These educational materials provide information on how to manage stress with a healthy lifestyle.
5. If you are randomly assigned to Group B (the *first experimental condition*), you will be asked to download Moodivate to your smartphone. Moodivate focuses on tracking daily activities, recording daily mood, and identifying new activities to complete that may help improve mood. You will be asked to use Moodivate regularly, at least once per day, for the study duration. Moodivate is experimental and private health information will be collected within Moodivate.
6. If you are randomly assigned to Group C (the *second experimental condition*), you will also be asked to download Moodivate to your smartphone. If you are randomly assigned to Group C, your primary care provider at MUSC will be sent a message via the electronic health record to alert them that you are enrolled in this trial and of your treatment group. Your provider will be provided access to a Moodivate provider portal that was also developed by our team. This provider portal will allow your primary care provider to review your use of Moodivate. It is up to your primary care provider how often, if at all, they decide to review this portal and whether they will use this provider portal as they work with you on the management of depressed mood. As part of this study, we are interested in examining how frequently providers utilize the Moodivate provider portal. Both Moodivate and the provider portal are experimental and private health information will be exchanged between Moodivate and the provider portal.
7. All participants will be asked to complete questionnaire measures throughout the study period. You will be asked to complete these questionnaires today, once per week over the next eight weeks, and then again twelve weeks from today. You will be e-mailed and/or text messaged (based on your preference) a link to complete these questionnaires and we request that you complete the questionnaires within 24 hours of receiving the link. You will be compensated for completion of the questionnaires if they are completed within 72 hours of receiving the link. Questionnaires will assess symptoms of depression as well as your experiences using Moodivate, if you received it as part of this study.
8. If you are in Group B or Group C, the study team will also access information regarding your use of Moodivate during the study period, including how frequently you use the app, for how long you use the app, and what you do within the app.
9. For all participants, we will collect cost data for all inpatient, outpatient and emergency department (ED) care that you receive at MUSC. We will also obtain similar claims data from South Carolina's Revenue and Fiscal Affairs Office, which maintains data on inpatient and ED

utilization across the state. These data will be collected for a period of two years prior to your study enrollment data through two years following your study completion date. The purpose of collecting this cost data is to examine any potential cost-savings associated with use of Moodivate.

C. DURATION

Participation in this study will take about 12 weeks. Each set of questionnaire measures will take approximately 20 minutes to complete. If you download Moodivate as part of the study, we will ask that you use it once per day for at least 5 to 10 minutes at a time.

D. RISKS AND DISCOMFORTS

1. **Frustration**: You will complete questionnaires throughout the duration of this study. The questions that will be asked may be sensitive in nature and make you feel uncomfortable. You may be asked personal questions that you find distressing. You may refuse to answer any question(s) that you do not wish to answer. Similarly, if you receive Moodivate, you may become frustrated while using the app. To mitigate this risk, we invite you to contact us via phone or e-mail to troubleshoot difficulties with the app.

2. **Emotional distress**: Your depressive symptoms may become worse throughout the course of this study. Depressive symptoms will be monitored weekly by the Principal Investigator. Should your symptoms of depression worsen, or should you have thoughts of harming yourself throughout the study, the Principal Investigator will contact you via phone and will provide referrals for local mental health resources for depression treatment. The Principal Investigator will suggest that you seek treatment and then will follow-up with you via phone one week later. In the event that you report suicidal ideation either during study assessments, the Principal Investigator will complete a risk assessment with you over the phone. The Principal Investigator will ask you questions about your thoughts of harming yourself, including a likelihood of harming oneself imminently and a plan for committing suicide. If you report an imminent likelihood of harming yourself or a plan for committing suicide, the Principal Investigator will call emergency services and will remain on the phone with you until emergency services arrives. In the event that you evidence clinical deterioration, you will be allowed to continue in the trial.

3. **Data breach**: There is a risk of a data breach of health information from the Moodivate servers during the course of the study. In the event of a data breach, all app users will be notified via email.

4. **Confidentiality**: There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. Efforts will be taken to ensure that all information you provide throughout the course of this study is kept confidential. In order to ensure confidentiality, all participant information will be identified with a number and kept under lock and key or on a secure MUSC server accessible only to our study team. Your information may be shared with representatives of the Medical University of South Carolina or governmental authorities if you or someone else is in danger or if we are required to do so by law.

E. MEDICAL RECORDS

If you are an MUSC patient you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Documentation of your participation in this study will be included in the medical record and results of research tests or procedures may be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

F. BENEFITS

There will be no guaranteed direct benefit to you from participating in this study. It is hoped that the information gained from the study will help in the treatment of future individuals with depressive symptoms.

G. COSTS

Your normal data usage and rates will apply while using Moodivate. There are no other costs to you associated with participating in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be compensated via electronic gift cards (e.g., Amazon) which will be emailed and/or text messaged to you for your participation in this study. You will be paid $10 for completion of each set of study questionnaires completed within 72 hours of receiving the emailed/text messaged link to complete the questionnaires. You will receive an additional $40 for completing all sets of questionnaires. Total compensation for completing all aspects of this study is $140.

Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 12	Bonus
$10	$10	$10	$10	$10	$10	$10	$10	$10	$10	$40
Total Compensation = $140										

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at MUSC. If you decide to withdraw, we ask that you contact Dr. Dahne to let her know that you are withdrawing from the study.

J. DATA SHARING

Information about you (including your identifiable private information) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

K. DISCLOSURE OF RESULTS

Clinically relevant research results, including individual research results, will not be disclosed to you as a part of this study.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to

review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

N. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

O. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

P. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below for paper consents, or scroll down and select your choice electronically:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Q. CONFIDENTIALITY

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are

subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Jennifer Dahne (843-876-2280, dahne@musc.edu). I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____

Signature of Person Obtaining Consent Date

_____

*Name of Participant

_____

Signature of Participant Date