INFORMED CONSENT FORM

Official Study Title

Optimizing Care for Cancer Survivors With Depression (OASIS): Project 3

ClinicalTrials.gov Identifier: NCT06930729

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MUSC
Medical University of South Carolina
Changing What's Possible

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: **Optimizing Care for Cancer Survivors with Depression (OASIS): Project 3**

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 different depression treatment approaches among cancer survivors. A cancer survivor is defined as anyone who is living and has been diagnosed with cancer.

If you agree to participate, you will be randomly assigned, like pulling a number out of a hat, to either download a mobile app for depression treatment, called "Moodivate", or to receive telehealth depression treatment sessions. Approximately two in three of participants enrolled will receive the mobile app and the remaining one in three will receive depression treatment via telehealth. The depression treatment via the Moodivate app is investigational. If you download Moodivate, you may later be assigned to also receive depression treatment via telehealth based on your response to the Moodivate app. Based on how you use the app during the first two weeks, a determination will be made as to whether that intervention approach is appropriate for you. If it is deemed that the app is not appropriate for you, you will be reassigned to receive treatment via telehealth. If you are reassigned to received telehealth treatment, this will not extend your participation in this study. You will be asked to either use the Moodivate app and/or receive depression treatment via telehealth for a period of 10 weeks.

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 and participating in this trial. In addition to these electronic questionnaires, if you are asked to download Moodivate, our study team will collect data regarding your use of Moodivate, such as how frequently you use the app, for how long you use the app, and what you do within the app. Participation in this study will take about 24 weeks, beginning today. All research visits will occur remotely and there are no in-person visits.

Participation in this study may help improve options for emotional wellness for cancer survivors. 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 or your oncology care team to discuss other available treatments for depressed mood.

If you are interested in learning more about this study, please continue to read below.

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 research study is to evaluate different depression treatment approaches among cancer survivors. The depression treatment via the Moodivate app is investigational. A cancer survivor is defined as anyone who is living and has been diagnosed with cancer. You are being asked to participate in this study because you have been identified as a cancer survivor with elevated symptoms of depression. The investigator in charge of this study is Dr. Jennifer

Dahne. The study is sponsored by a grant from the Hollings Cancer Center. Portions of the research team's salaries may be paid by this grant. The study is being done at one site. Approximately 45 people will take part in this study, all at the Medical University of South Carolina (MUSC).

Dr. Dahne, the principal investigator, is a co-owner of the company Behavioral Activation Tech LLC which holds the intellectual property rights to the Moodivate app used in this research protocol. Intellectual property refers to creations of the mind, such as inventions. MUSC COI Office has reviewed Dr. Dahne's disclosure in relation to this study. This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study.

B. PROCEDURES

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

1. The research team will collect information from your screening questionnaire and medical record such as Oncological diagnoses to be used for research purposes.

2. You will be randomly assigned, like pulling a number out of a hat, into one of two groups. You will not have the opportunity to choose which group you are in. You have a two in three chance of being assigned to Group A and a one in three chance of being assigned to Group B.

3. If you are randomly assigned to the Moodivate app group (Group A), you will be asked to download the Moodivate app to your smartphone. Moodivate is a Behavioral Activation (BA) therapy app. BA is depression focused therapy which include 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 next 10 weeks. Moodivate is an experimental app and health information (for example, information about your mood) will be collected within Moodivate. 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. Based on how you use the app during the first two weeks, a determination will be made as to whether that intervention approach is appropriate for you. If it is deemed that the app is not appropriate for you, you will be reassigned to receive treatment via telehealth. If you are reassigned to received telehealth treatment, this will not extend your participation in this study.

4. If you are randomly assigned to the standard depression treatment via telehealth group (Group B), you will not download the Moodivate app, however you will receive depression treatment with a mental health provider. You will be scheduled for 8 telehealth sessions over the next 10 weeks. All telehealth sessions will be audio/video recorded and destroyed 12 months after study completion. Prior to your first telehealth session, the study team will mail you a patient workbook.

5. Regardless of the group you are assigned to, you will be asked to complete questionnaires throughout the study period. You will be asked to complete these questionnaires today, 12 weeks, 16 weeks, 20 weeks, and 24 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 downloaded it as part of this study.

6. In addition to the questionnaires, all participants will be asked to provide blood samples remotely at two separate time points, after you enroll and again at your week 12 follow-up. After today's appointment, the study team will mail you a blood collection kit and another before your week 12 follow-up. A study team member will schedule a video call with you to take place within the next week to help walk you through providing your blood sample. We will also schedule your week 12 video call where you'll provide your blood sample again and complete your week 12 surveys. Each blood collection sample will be labeled with your unique participant identification number. The device is a small, wearable device designed to collect capillary blood from the upper arm in a minimally invasive and nearly painless way. The device sticks to the skin on your arm with a light adhesive. When the button of the device is pressed, a vacuum forms and a lancet pricks the surface of the skin. The vacuum draws blood out of the capillaries and into a container attached to the bottom of the device. Some people refer to these devices as a needle-free system since it does not use a hollow venipuncture needle to enter a vein. The device will collect less than one teaspoon of blood. After you collect your blood sample, you'll send it back to the study team with the provided prepaid shipping label where it will be shipped to a lab for analysis. The lab will test blood samples to look for certain proteins, like cytokines, that can show what's happening in the body.

7. At the end of the study, you may be invited to participate in a 30-minute interview with a member of our team. This call will be audio/video recorded. The purpose of this interview is so you may provide helpful feedback about your experiences using the Moodivate app and/or standard telehealth depression treatment.

Your participation in this study is voluntary. If you decide to participate, you are free to withdraw at any time without penalty. You may be withdrawn from the study without your consent if the researchers believe it is in your best interest of if you fail to follow study procedures.

C. DURATION

Participation in this study will take about 24 weeks. Each set of questionnaire measures will take approximately 10-20 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. The standard telehealth therapy sessions will take about 1 hour each and you will be asked to complete 8 sessions over up to 10 weeks (8 hours total). If you're invited to participate, the interview will take approximately 30 minutes to complete. The first video call to complete your blood sample will be no more than 30 minutes. The second video call to collect your blood sample and complete your week 12 surveys will take about 1 hour. All research visits will occur remotely and there are no in-person visits.

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 download Moodivate, you may become frustrated while using the app. To lessen this risk, we invite you to contact us via phone or e-mail to troubleshoot difficulties

with the app.

2. **Emotional distress**: Your symptoms of depression may become worse throughout the course of this study. Depressive symptoms will be monitored weekly by the study team. Should your symptoms of depression worsen, or should you have thoughts of harming yourself throughout the study, the Principal Investigator or another member of the research team will contact you via phone and will provide referrals for local mental health resources for depression treatment and appropriate follow-up. However, you will be allowed to continue in the trial. In the event that you report suicidal ideation during the course of the study, a clinically trained study team member will complete a risk assessment with you over the phone. If you report an imminent likelihood of harming yourself or a plan for committing suicide, emergency services will be called and will be provided with your contact information and location.

3. Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting is possible, although unlikely.

4. **Data breach**: There is a risk of a data breach of health information (e.g., daily mood ratings, activities, values) from the Moodivate servers during the course of the study. A data breach is unauthorized access to information within the mobile app. The Moodivate servers are not maintained by MUSC, therefore MUSC cannot control security measures on a server that is housed outside of MUSC. Moodivate is an experimental app and in the event of a data breach, all app users will be notified via email.

5. **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 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.

6. **Randomization:** The treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

7. **Unknown risks:** The experimental treatments may have unknown side effects. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating in the study.

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. However, there is a possibility of reduced depressive symptoms. It is hoped that the information gained from the study will help in the treatment of future cancer survivors with depressive symptoms.

G. COSTS

Your normal data usage and rates will apply while using Moodivate or if you choose to join your tele-health sessions from your cellular device. The Moodivate app will be provided at no cost to you. 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 a pre-paid debit card called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule below. Details of the debit card system are explained on an additional sheet.

ClinCard is administered by an outside company called Greenphire. Greenphire will be given your name, address, SSN and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study that you are participating in.

You will be paid $50 for completion of the baseline questionnaires that you complete today once your blood sample has been received by the study team. You will receive $50 for week 12 surveys once blood sample has been received by the study team, $25 for week 16, $25 for week 20, and $50 for week 24. To receive compensation each set of study questionnaires must be completed within 72 hours of receiving the emailed/text messaged link. If you complete all follow up surveys and both blood samples are returned to us, you'll receive a $50 bonus. Total compensation for completing all study questionnaires is $250 and $300 if you're also invited to complete the post-study interview with a member of our team.

Baseline	**Week 12**	**Week 16**	**Week 20**	**Week 24**	**Bonus**	**Interview**
$50	$50	$25	$25	$50	$50	$50
	Total Compensation: $250 (up to $300 if you participate in the post-study interview)					

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

Your alternative is not to participate in this study and to contact your primary care provider or your oncology care team to discuss other available treatments for depressed mood. 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. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

K. DATA SHARING

Information about you 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.

L. DISCLOSURE OF RESULTS

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

M. 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

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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.

N. 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.

O. COLLECTION OF SPECIMENS

This study will involve blood collection as part of your participation in this study. The study team will mail you a blood collection kit to provide blood samples at two time points (the day you enroll and week 12). Each blood collection sample will be labeled with your unique participant identification number. The device is a small, wearable device designed to collect capillary blood from the upper arm in a minimally invasive and nearly painless way. The device sticks to the skin on your arm with a light adhesive. When the button of the device is pressed, a vacuum forms and a lancet pricks the surface of the skin. The vacuum draws blood out of the capillaries and into a container attached to the bottom of the device. Some people refer to these devices as a needle-free system since it does not use a hollow venipuncture needle to enter a vein. The device will collect less than one teaspoon of blood. After you collect your blood sample, you'll send it back to the study team with the provided prepaid shipping label where it will be stored at -80 degrees Celsius and shipped to a lab for analysis. The lab

will test blood samples to look for certain proteins, like cytokines, that can show what's happening in the body. The samples will not be shared with any other investigators and will be used for research purposes only. All blood samples will be stored for up to 1 year and destroyed upon lab analysis. Your blood samples will not be used for commercial profit and will not be analyzed for genome sequencing.

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. Please scroll to the bottom of the screen to provide an electronic signature.

_____

Signature of Person Obtaining Consent Date

_____

*Name of Participant

_____

Signature of Participant Date

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