MomMoodBooster Randomized Components Trial: A program for perinatal depressed female Veterans

IRB#: 202102537

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11-19-2021

	RESEARCH CONSENT FORM FOR IRB USE ONLY APPROVED BY: IRB-03 VA Only IRB ID #: 202102537 APPROVAL DATE: 11/19/21

Participant Name:_____ **Date:**_____

Title of Study: MomMoodBooster Randomized Components Trial

Principal Investigator: Emily B. Kroska Thomas, PHD **VA Facility:** Iowa City, Iowa

SUMMARY

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

In this study, we hope to continue to learn how effective the MomMoodBooster program is overall in treating perinatal and postpartum depression in women veterans. We are also interested in the effects of phone coaching on depressive symptoms.

This study is being funded by the Veterans Rural Health Resource Center. This means that the University of Iowa is receiving funds to support the activities that are required to conduct this study.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

Your participation in this research will last about 6 months. The first assessment of the study will include questionnaires about your mood and behaviors, and these questionnaires should take no more than 60 minutes to complete. The first 6 weeks involves working through the intervention program curriculum by completing weekly lesson modules. We anticipate that it will take approximately 30-60 minutes to work through each lesson; however, you are free to spend as much time as you would like working through and reviewing the modules. You can work through the modules at your own pace. There is no limit to the number of times you can read each lesson and complete the activities. After completing the curriculum, you will be mailed a series of follow-up assessments to be completed at 3 months post-program enrollment. Completing these questionnaires may take as long as an hour, but typically these assessments can be completed in 20-30 minutes. At approximately 14 and 20 weeks post-enrollment, we will offer you two “booster” sessions that are aimed at helping you consolidate the gains that you have made and to learn new material to help you stay well. We will also send you a follow-up assessment to complete at six months post-program enrollment, and this assessment will take about 20-30 minutes to complete

Over the following 6-8 weeks, you will work through the MomMoodBooster program. The intervention program includes six modules that are to be completed in order at the rate of one module per week. You will also be assigned to one of two groups at random, like flipping a coin. One group will include the online portion of the program plus weekly phone calls from a coach, and the other group will receive the online portion of the program and symptom assessment calls from a coach. If you are assigned to the coaching group, you will receive weekly phone calls lasting 15-30 minutes from a coach who will monitor your mood and encourage you to use the program and to practice the recommended strategies. The coaching calls will pertain to the online material and apply the content to your life and circumstances. Although the online content can be completed at your convenience, the coaching calls will need to occur during business hours (8:00 – 5:00 PM CST) unless otherwise arranged with the research team. Your coach will take notes in the secure database about the conversation. The program is designed so that your coach will know which aspects of the program you have and have not used. This feature makes it possible for your coach to answer specific questions about the program or provide you with feedback about the activities you have completed. If you are assigned to the coaching group, you will also receive text message reminders in advance of your coaching calls. The purpose of these calls is to check on your mood and determine whether the online program is still appropriate or contact with a health care professional is required.

At three and six months after the date of your program enrollment, we will ask you to complete another series of questionnaires about your mood and coping strategies, and we will ask you to return them to us by mail. Approximately 14 and 20 weeks after program enrollment, we will offer you two new "booster" sessions, which are optional and include more content related to perinatal depression.

If you are still experiencing significant symptoms of perinatal or postpartum depression at the three-month follow up assessment or the six-month follow-up assessment, you will be offered a referral to your local VA Medical Center or to other appropriate services in your local area.

If at any time during the study we feel that there is a significant risk that you may harm yourself or harm others, we will instruct you to contact emergency services at your local VA Medical Center and/or go to the nearest hospital. The Principal Investigator for this study, Dr. Emily B. Kroska Thomas, will be informed that this has occurred and will contact you to ensure that you have sought appropriate treatment.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may choose to volunteer for this study for different reasons. Being that MomMoodBooster is an online-based intervention program, participation does not require travel to any VA facility and may be utilized in any location where you have a working smartphone/tablet/computer capable of internet access. Additionally, MomMoodBooster incorporates key components from an effective, evidence-based treatment option for postpartum depression, Cognitive Behavioral Therapy (CBT). Furthermore, you will be in contact with a mental health professional during your time in the study.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may choose not to volunteer for this study for different reasons. Working through the weekly program modules and engaging in phone coaching calls will require your time to complete them. Based on your availability, this may be difficult or impossible for you. Additionally, you may experience embarrassment or discomfort in answering questionnaires, interview questions, or calls with the research team.

Before you decide whether or not to be in this study, you are free to discuss with your doctor other treatment options that are available to you. However, you may participate in this study even if you pursue other therapies, including medication therapy, psychotherapy, or alternative and complementary therapies (CAM).

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. If you decide to be in this study, you may stop participating at any time. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer or if you choose to stop participating in the study at any time.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

Participant Name:_____ **Date:**_____

Title of Study: MomMoodBooster Randomized Components Trial

Principal Investigator: Emily B. Kroska Thomas, PHD **VA Facility:** Iowa City, Iowa

The person in charge of the study is Dr. Emily B. Kroska Thomas of the Iowa City VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: (319)-467-1691.

Participant Name:_____ **Date:**_____

Title of Study: MomMoodBooster Randomized Components Trial

Principal Investigator: Emily B. Kroska Thomas, PHD **VA Facility:** Iowa City, Iowa

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are either pregnant or have recently had a baby, completed a series of screening questionnaires, and have experienced depressive symptoms at some point during pregnancy or since the birth of your baby.

With this research we hope to learn how practical and effective certain components are within an online-based intervention program for the treatment of perinatal and postpartum depression in women veterans engaging in VA services. The purpose of these calls is to check on your mood and determine whether the online program is still appropriate or contact with a health care professional is required. We are also interested in the role of weekly phone coaching throughout the program. The program is based upon central Cognitive Behavioral Therapy (CBT) elements that have been found to be effective for the treatment of perinatal and postpartum depression. We have tested this program previously and have evidence that it is effective.

HOW LONG WILL I BE IN THE STUDY?

Approximately 200 women will take part in this study conducted by investigators at the University of Iowa and the Iowa City VA Health Care System. This program has been in place since 2013, undergoing several iterations, and we hope to continue to improve upon its components in the coming years. Your participation in the project will last approximately 6 months.

First, we will ask you to complete a set of questionnaires that will be sent by mail. The questionnaires should take no more than 60 minutes to complete. The first 6 weeks involves working through the intervention program curriculum by completing weekly lesson modules. We anticipate that it will take approximately 30-60 minutes to work through each lesson; however, you are free to spend as much time as you would like working through and reviewing the modules. There is no limit to the number of times you can read each lesson and complete the activities. If you are assigned to the coaching group you will also be receiving weekly phone calls lasting 15-30 minutes. These calls are intended to monitor your mood and encourage you to use the program and to practice the recommended strategies. Your coach will take notes in the secure database about the conversation. If you are assigned to the online group, you will complete the online intervention content without coaching calls. A coach will call you during sessions 1, 3, and 5 to assess your mood and thinking. Although the online content can be completed at your convenience, the coaching calls will need to occur during business hours (8:00 – 5:00 PM CST) unless otherwise arranged with the research team. After completing the curriculum, you will be mailed a series of follow-up assessments to be completed at 3 months post-program enrollment. Completing these questionnaires will take no more than 60 minutes. At approximately 14- and 20-weeks post-enrollment, we will offer you two “booster” sessions that are aimed at helping you consolidate the gains that you have made and to learn new material to help you stay well. If you are assigned to the coaching group you will also receive 2 phone coaching calls along with these booster sessions. We will also send you a follow-up assessment at 6-months post-program enrollment regardless of whether you choose to take part in the booster sessions.

Participant Name:_____ **Date:**_____

Title of Study: MomMoodBooster Randomized Components Trial

Principal Investigator: Emily B. Kroska Thomas, PHD **VA Facility:** Iowa City, Iowa

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you are interested in continuing your participation in the study, please sign and return this document. We ask also that you complete it and return the accompanying study questionnaires. For all study interviews and questionnaires, you are free to skip any questions that you would prefer not to answer. Additionally, please feel free to ask any questions that arise for you at any time. If your pregnancy status changes before or during your participation in this study, please reach out to the research staff to inform them of this change as soon as possible. Upon receipt of the signed document, we will contact you by phone to help you set up your program account.

Over the following 6-8 weeks, you will work through the MomMoodBooster online intervention program. The intervention program includes six lesson modules that are to be completed in order at the rate of one lesson per week. You will also be assigned to one of two groups at random, like flipping a coin. One group will include the online portion of the program plus weekly phone calls from a coach, and the other group will receive the online portion of the program and will receive calls from a coach to conduct assessments of your symptoms. If you are assigned to the coaching group, you will receive weekly phone calls lasting 15-30 minutes from a coach who will monitor your mood and encourage you to use the program and to practice the recommended strategies. The program is designed so that your coach will know which aspects of the program you have and have not used. Your coach will take notes in the secure database about the conversation. Notes from the coaching calls and your self-report assessments will be stored in a secure online database called REDCap. The online intervention makes it possible for your coach to answer specific questions about the program or provide you with feedback about the activities you have completed. You will also receive text message reminders in advance of your scheduled calls. Although the online content can be completed at your convenience, the coaching calls will need to occur during business hours (8:00 – 5:00 PM CST) unless otherwise arranged with the research team. Please keep your phone coaching appointments. If you miss an appointment, please contact the project coordinator at (866)-849-6636 during business hours (8:00 AM – 5:00 PM CST) to reschedule as soon as you know you will miss the appointment. During weeks 1, 3, and 5 of the program, you will be contacted by phone to complete a short 9-item questionnaire and brief interview.

At three and six months after the date of your program enrollment, we will ask you to complete another series of questionnaires about your mood and coping strategies, and we will ask you return them to us by mail. Completing these questionnaires will take no more than 30 minutes. Approximately 14 and 20 weeks after program enrollment, we will offer you two new "booster" sessions. We will ask that you also complete a series of questionnaires at six-months post-program enrollment and return them to us by mail. These questionnaires will also take no more than 30 minutes to complete.

If you still are experiencing significant symptoms of perinatal or postpartum depression at the three-month follow-up assessment or after the two booster sessions, you will be offered a referral to your local VA Medical Center or to other appropriate services in your local area.

If, at any time during the study, we feel that there is a significant risk that you may harm yourself or harm others, we will instruct you to contact emergency services at your local VA Medical Center and/or go to the nearest hospital. The Principal Investigator for the study, Dr.

Emily B. Kroska Thomas, will be informed that this has occurred and will contact you to ensure that you have sought appropriate treatment.

Throughout your participation in this study, you will interact with multiple study staff:

- Principal Investigator: Dr. Emily B. Kroska Thomas, Ph.D.
- Project Coordinators: Manny Stegall
- Phone Coaches: Alyssa Schneider, Ti Hsu, Shana Harris, Natalie McClellan
- Research assistants also are part of our team

The program being evaluated in this study, MomMoodBooster, is an online-based intervention program. The study procedures will occur primarily online with whichever internet-capable device(s) you choose to utilize while participating in the study (i.e., Smartphone, tablet, computer). Additional study procedures include phone calls, which will occur wherever you are engaging in a phone call while participating in the study. Please choose to take our calls in a private space where you can speak freely. If you do not answer our phone calls, we will call you no more than three times without a returned contact. After three calls, we will cease calling you for phone coaching, but we will mail you the follow-up questionnaires unless you explicitly tell us that you do not wish to participate further.

Your information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies. We will keep your contact information in order to contact you about future research studies. When we contact you, you can decide whether you would like to participate in those studies at that time, and these studies will have a separate informed consent document.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any intervention study has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks listed. Rare, unknown, or unexpected risks also may occur. In addition to these, there may be other unknown risks, or risks that we did not anticipate associated with being in this study.

You may experience some embarrassment or social discomfort in answering questionnaires or interview questions. You are free to skip or not answer any questions you wish. The risk of loss of confidentiality will be minimized by storing data and other documents with personal data in locked filing cabinets, on password-protected computers, and in a secure online storage platform called REDCap. Additionally, there is a risk of loss of confidentiality if there is a duty to warn, that is, we are compelled to inform another individual that you have expressed suicidal or homicidal intentions.

PHOTOGRAPHS, AUDIOTAPING, OR VIDEOTAPING

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recordings to be made of you by the research staff while you are participating in this study. The said voice recording is intended for the following purposes: To monitor the quality and reliability of phone coaching sessions and interviews; and to facilitate training of the interventionist team.

The study team has also explained that you will not receive any royalty, fee, or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded, and you may rescind your consent for up to a reasonable time before the voice recording is used.

Below please indicate whether we have your permission to audiotape the phone calls as part or your participation, and provide your initials.

Yes No_____ Initials

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will benefit from being in this study, but our previous work suggests that women may experience reduced depressive symptoms and report satisfaction with the intervention program. Moreover, we hope that in the future other perinatal and postpartum women might benefit from this study because of knowledge gained regarding a new treatment approach for depression during and/or after pregnancy.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Before you decide whether to be in this study, you are free to discuss with your doctor other treatment options that are available to you. However, you may participate in this study even if you pursue other therapies, including medication therapy, psychotherapy, or alternative and complementary therapies (CAM).

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

We will keep your participation in this research study confidential to the extent permitted by law. However, there is a risk of loss of confidentiality if there is a duty to warn, that is, we are compelled to inform another individual that you have expressed suicidal or homicidal intentions. Additionally, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Federal government regulatory agencies,
- Oregon Research Institute (Contract research Organization)
- Auditing departments of the University of Iowa, and
- The University of Iowa/Iowa City Veterans Affairs Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, all data will be coded by participant identification number only and will be stored in locked file cabinets. Computer data will be entered by participant identification number only, and all computer files will be password protected. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified. None of your personal information will be sent to the Oregon Research Institute. It will simply host the online MomMoodBooster program, but it will have access to the Internet Protocol address (IP address) of the computer that you would use

when you log into the program. Identifiers might be removed from the identifiable private information that is collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You may have any additional costs for being in this research study. Note that use of internet or cellular data may incur fees with your internet or phone providers. You are responsible for these costs, and you should carefully select where you choose to complete the intervention to avoid additional fees.

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid $25 for completing the baseline assessment questionnaires. You also will be paid $25 for completing the follow-up questionnaires, which you will receive three and six months after program enrollment, so a total of $75 is possible.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

DO I HAVE TO TAKE PART IN THE STUDY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you choose to take part in this research study now, and during the course of participation decide to withdraw from the study, we may continue to review the data already collected for the study, but will not request any future data from you.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen if in our judgment it would not be safe for you to continue in the study because your symptoms have worsened. It is important that interactions between the research team and participants are characterized by mutual respect. If at any time the research team feels unsafe, threatened, or disrespected, we might decide to end your participation in this research study earlier than planned. If we end your participation, we will offer to refer you to your local VA Medical Center or will provide you with a list of mental health resources in your community. Additionally, if we feel that the worsening of your symptoms

presents an imminent risk to your safety or the safety of others, we will instruct you to contact emergency services at your local VA Medical Center and/or go to the nearest hospital. The Principal Investigator for the study, Dr. Emily B. Kroska Thomas, will be informed that this has occurred and will contact you to ensure that you have sought appropriate treatment.

REGISTRY INFORMATION

We will keep contact information (name, address, phone number, My HealtheVet) to contact you about participation in future studies. In such cases, you are not obligated to participate in future studies, and if you do, a separate Consent Document would be signed for these future studies.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Emily Kroska Thomas, Ph.D. at 319-467-1691 or Emily-kroska@uiowa.edu. Dr. Thomas and lab staff are available during business hours (8:00 AM – 5:00 PM CST). If you experience a research-related injury, please contact: Dr. Thomas at 319-467-1691 or Emily-kroska@uiowa.edu. If at any time you have an emergency regarding your study treatment, please call Dr. Thomas at 319-467-1691 or 319-467-4615 or Emily-kroska@uiowa.edu. If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking “Info for Public” on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Hawk IRB at 319-335-6564 and request to speak to an analyst from IRB-03, specific to VA studies. If you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we’ll promptly provide you with that information

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Emily B. Kroska Thomas, Ph.D., or Manny Stegall, BS, Alyssa Schneider, M.P.H., Maria Buri, or another research team member has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

Participant Name:_____ **Date:**_____

Title of Study: MomMoodBooster Randomized Components Trial

Principal Investigator: Emily B. Kroska Thomas, PHD **VA Facility:** Iowa City, Iowa

By signing this document below, I voluntarily consent to participate in this research study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date