Consent and Authorization Document

Key Information about this Research

You are invited to join a research study about Maternal Mental Health Access (MMHA or "Mama" study). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Please take time to read this document carefully. Taking part in this study is your choice.

Approximately one in seven women experience depression and/or anxiety during and after pregnancy. Prevention programs using mindfulness-based cognitive behavioral therapy (MBCT) have been shown to be effective at preventing postpartum depression and reducing symptoms of depression and anxiety. However, these need to be more convenient and meet the preferences of diverse individuals. Most are not offered by healthcare systems.

The purpose of the Mama study is to evaluate if a prevention program will work in a healthcare system. The program is available in YoMingo®, an internet-based app provided free to all patients at the University of Utah. YoMingo® offers easy access to educational articles and videos on topics such as pregnancy, childbirth, newborn care, mental health, and more.

You will be granted access to the perinatal depression prevention program in YoMingo® if you choose to participate in the Mama study. All participants in the program will have access self-guided modules. Additionally, you will be randomly assigned to a "paired choice" group. Depending on your assigned group, you will also choose to participate in 4 group videoconference sessions or a Facebook discussion board. You will also complete surveys 5 times during the study. You will receive the surveys by email. Each survey takes about 10-15 minutes to fill out.

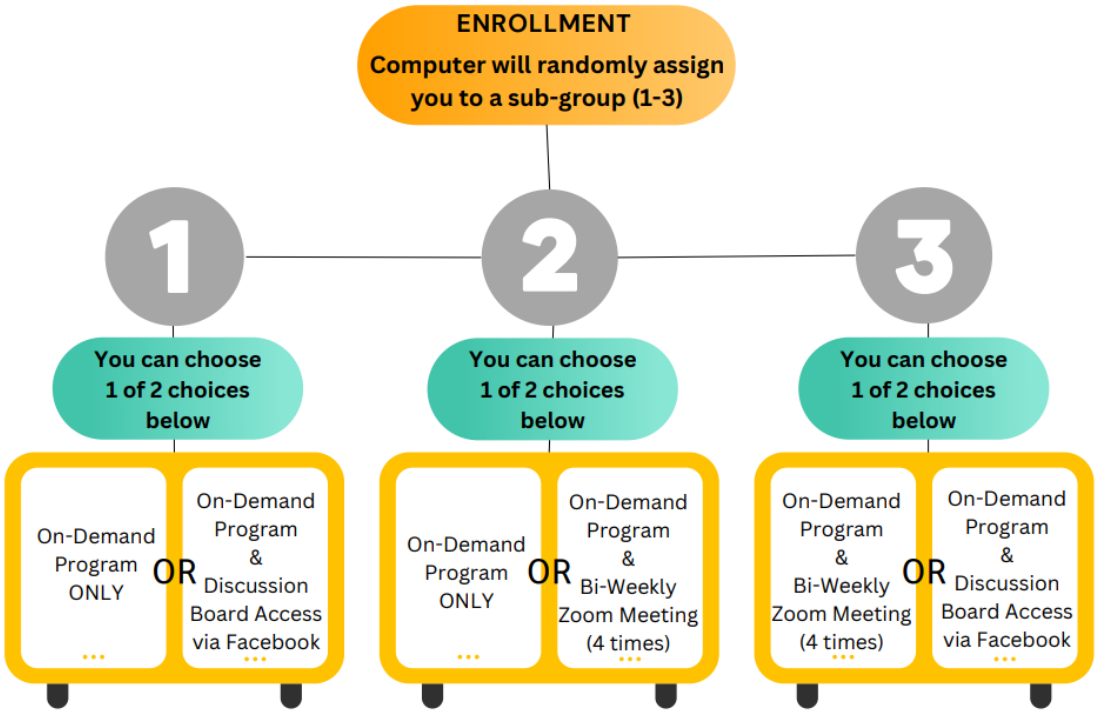
You will receive a $20 reloadable, prepaid card after completing each study survey (a total of up to $100). You will also receive a $20 reloadable, prepaid card if you attend a focus group session. The risks of participating in this study are small. You may feel upset when thinking or talking about personal experiences with depression and/or anxiety. We cannot promise any benefits to you from being in the Mama study. However, possible benefits may include learning more about your mental health, reducing depression and anxiety and preventing postpartum depression. It may also increase a sense of support and community.

Participating in this research is voluntary. Whether you choose to participate or not, your choice will not affect your relationship with your healthcare providers or your access to YoMingo®. This study is being conducted by Dr. Gwen Latendresse, PhD, CNM, FACNM, FAAN, at the University of Utah's College of Nursing. Ask us if there is anything that is not clear or if you would like more information (385-444-0511: momsmentalhealth@utah.edu).

STUDY PROCEDURES

For the Mama study, you will access the program in YoMingo®. You may already be registered for YoMingo® since it is available free to all UHealth patients. If you are not a UHealth patient, you will be given free access by the study team. You do not have to participate in this study to access YoMingo® or the maternal mental health information on the app. But, access to the perinatal depression prevention program will be available in YoMingo® for study participants only. If you decide to participate in this study, you will be granted access to the prevention program and randomly assigned to a "paired choice" group. This means you will choose one of two ways to participate. The choices depend on which group you are assigned to:

1. <u>On-demand modules or on-demand PLUS join an on-line discussion board</u>: the on-demand program includes 8 different learning modules, each containing articles for you to read and audio-video files for you to view/listen to at your own convenience (any time day or night). The on-line discussion board (moderated by a trained facilitator) will be held in a private Facebook® group where study participants can join discussions with others as they wish.
2. <u>On-demand modules (as described in option # 1 above) or on-demand PLUS 4 virtual group sessions</u>: live group sessions (which will include other participants and a trained facilitator) will be held via Zoom for one hour every two weeks.
3. <u>On-demand modules (as described in option # 1 above) plus an on-line discussion board OR on-demand modules plus 4 virtual group sessions (as described above).</u>



The prevention program described above is 8 weeks in duration. The program is designed to teach women skills that can prevent perinatal (postpartum) depression and anxiety. The program is based on an evidence-based prevention program that includes Mindfulness-based Cognitive Behavioral Therapy (MBCT).

After participating in the 8-week program, you may be invited to attend a one-hour focus group to be held 2-4 weeks later via Zoom videoconference. The purpose of the focus group is to gather participants' feedback about the program. The focus group will consist of any participants who have completed the program and are interested in joining the focus group session.

All participants are asked to complete surveys to measure depression and anxiety symptoms at five (5) different time points during the study:

- Before starting the program
- Immediately after finishing the program (around 8 weeks after you start the program)
- Two (2) months after finishing the program
- Four (4) months after finishing the program
- Six (6) months after finishing the program

You will receive the surveys by email. Each survey takes about 10-15 minutes to fill out.

RISKS

The risks of participating in this study are small. You may feel upset when thinking or talking about personal experiences with depression and/or anxiety. These risks are similar to what you may experience when you talk about personal experiences with others. If you feel upset by this experience, you can tell the researcher, who can then provide community and national resources to help. There is also the possibility that the intervention facilitator may fail to detect depressive symptoms and/or suicidal/homicidal ideation. Participants are encouraged to tell the facilitator if they have thoughts of harming themselves or others.

We ask that participants never share with others what they see, hear, or read about others in the program (including from discussion boards and live group sessions). However, we cannot guarantee that this will not happen.

BENEFITS

We cannot promise any benefits to you from your being in the Mama study. However, possible benefits include learning more about your mental health, reducing risk for postpartum depression and symptoms of depression and anxiety. It may also increase a sense of support and community.

ALTERNATIVE PROCEDURES

You may choose not to be in this study. Whether you choose to be in the study or not, you will still continue to receive the same prenatal, birth, and postpartum care from your chosen healthcare provider and clinic. You do not have to participate in this study to access and use YoMingo® in the

University of Utah Health system. Participation in this study is not a substitute for your routine prenatal, birthing, and/or postpartum care and/or advice that you currently receive from your midwife, doctor, or mental health professional. You may discuss these options with your midwife, doctor, or mental health professional.

PERSON TO CONTACT

If you have questions, complaints, or concerns about this study, you can contact Dr. Gwen Latendresse, the study sponsor, at (801)587-9636. If you think you may have been harmed during this study, please call Dr. Gwen Latendresse at (801)587-9636. Dr. Latendresse can be reached at this number from 9am to 5pm Monday through Friday.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You have the right to refuse to participate. You also have the right to stop participating in the study at any time and for any reason without penalty. Whether you choose to participate or not, your choice will not affect your relationship with your healthcare provider (doctor, midwife, mental health professional, etc.) or the study team in any way.

COSTS AND COMPENSATION TO PARTICIPANTS

There is no cost to you or your insurance company to participate in this study other than cost you may already have for your internet or telephone use. However, depending on your current internet or telephone plan, it is possible that extra charges are added to your bill due to participating in the study. Please check your internet and/or telephone plan to see whether you might have additional charges. You are not required to buy an electronic device, but to use what you already have (computer, laptop, tablet, smart phone).

You will receive a $20 reloadable, prepaid card after completing each study survey (a total of $100 for completing all five surveys). You will also receive a $20 reloadable, prepaid card if you attend a focus group session (for a total of $120 for completing all five surveys and attending the focus group).

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.
We use the following information for research purposes:

- Demographic and identifying information (such as name, address, telephone number, and email address)
- Related medical information about you like personal and family medical history, current and past medications or therapies
- All information you provide during the course of study participation (such as your answers on the study questionnaires and completion of health assessments)

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your electronic medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- Any data collected during this study will be used for the purposes of this study alone, and data will not be used (in part or whole) for any other studies or projects.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team and University of Utah Health Sciences Center
    - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study complies with regulations protecting your rights.

- There are some cases in which a researcher is obligated to report issues, such as serious threats to public health or safety. For example, if you indicate that you or someone else is at imminent risk of harm (such as suicide or serious threats toward the well-being of others) we will contact the appropriate authorities in order to protect you and/or the public. The state of Utah has a mandatory reporting law for suspected or known child abuse/neglect. Should this occur, the study team will report to the Child & Family Services with the Utah Department of Health & Human Services.

- If we share your identifying information with groups outside of University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

- If you do not want us to use information about your health, you should not participate in this research. If you choose not to participate, you can still receive health care services at University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date