STUDY TITLE: “Mamma Mia” for perinatal health and wellness VCU INVESTIGATOR: Patricia Kinser, PhD, WHNP-BC, RN Associate Professor, VCU School of Nursing 804-828-9140

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: "Mamma Mia" for perinatal health and wellness

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NOTE: In this consent form, "you" always refers to the research participant.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.** This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may print an unsigned copy of this consent form to think about or discuss with family or friends before making your decision. Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to find out about ways to enhance well-being during pregnancy and the postpartum period (after the baby is born). We think that the "Mamma Mia" program and/or guided support from study staff ("Mamma Mia Plus") may be helpful because the program provides skills and information related to many important topics during and after pregnancy. For example, it contains content on topics ranging from mindfulness to infant development stages to breastfeeding strategies to ways to talk with partners and/or your healthcare providers about your experiences. This study will allow us to learn more about whether and how this program is helpful to women.

In particular, this study will compare findings in women who do not use the program ("usual care group") versus women who use the program ("Mamma Mia group") versus women who use the program and receive regular contact from study staff ("Mamma Mia Plus"). We will

assess well-being, depression, stress, and anxiety. We also want to understand whether certain factors (for example, women's age, type of healthcare provider, amount of social support) are related to the effects of the program. For women randomized to use the program, we will also collect information about the time you spend using it and the modules that you complete.

What will happen if I participate?

Usual prenatal and postpartum care involves regular visits with your women's health care provider while you are pregnant and after you have your baby. In this study, you will receive continue receiving usual care. In addition, you will be randomly assigned (like the flip of a coin) to participate in one of the following groups:

- The "usual care group", or
- the "Mamma Mia group" (which is to use the "Mamma Mia" program regularly), or
- the "Mamma Mia Plus group" (which is to use program regularly plus receive regular contact with our study staff).

You have 1 chance in 3 of being assigned to each of the three groups. You have an equal chance of being assigned to any one of the groups.

If you are randomized to the usual care group, you will be asked to do the following things:

1. Complete survey questions today.
2. Complete survey questions every few months (see schedule below).

If you are randomized to the "Mamma Mia group", you will be asked to do the following things:

1. Complete survey questions today.
2. Use the "Mamma Mia" program on a regular basis (on average: weekly for about 10 minutes) from now until you are six months postpartum; you will receive an email reminder to complete modules when they should be completed.
3. Complete survey questions every few months (see schedule below).

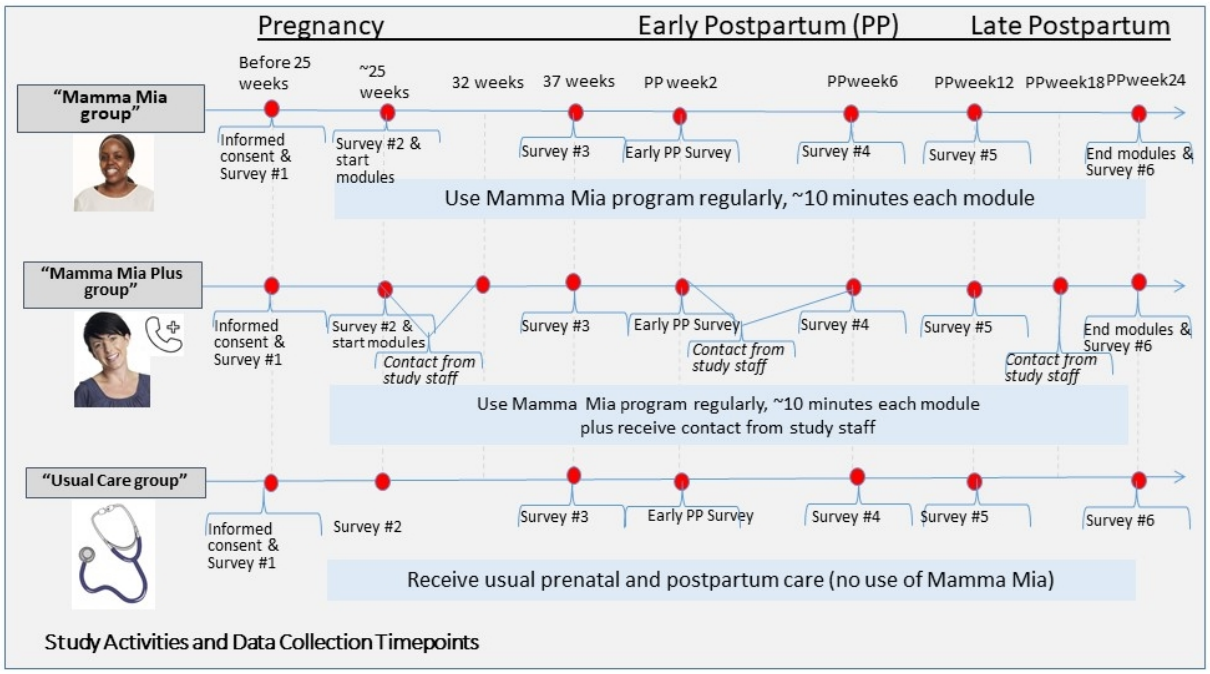
If you are randomized to the "Mamma Mia Plus group", you will be asked to do the following things:

1. Complete survey questions today.
2. Use the "Mamma Mia" program on a regular basis (on average: weekly for about 10 minutes) from now until you are six months postpartum.
3. Complete survey questions every few months (see schedule below).
4. You will receive phone calls or emails or texts (depending upon your preference) from study staff every few months.

You may also be contacted to share your experience with us through interviews with our study staff.

Your participation in this study will last up to 11 months. Approximately 2000 individuals will participate in this study.

There are six standard surveys that will be sent to all participants by email (called "Surveys #1-6" in the image below). You may also be invited to complete a survey shortly after the birth of your baby (called the "Early Postpartum Survey" in the image below).



About Mamma Mia:

Users of the Mamma Mia program progress through the intervention in a sequence of modules. Every day that a module should be completed, you will receive a notification with a reminder to access the app. By clicking on the reminder, you can access that particular day's session content. Modules involve a variety of information and activities; for example, there are guided mindfulness practices, information on breastfeeding, instructional videos on how to interpret your baby's cries, and discussions on how to have effective discussions with your partner or healthcare provider about your needs.

The program consists of three phases:

Phase 1- "Pregnancy Phase": The first phase starts in the second trimester (approximately gestational week 22) and consists of 11 sessions which you will complete on a weekly basis.
Phase 2- "Early Postpartum Phase": This phase starts when the infant is one to two weeks old, and lasts for six weeks, with three sessions per week.
Phase 3- "Late Postpartum Phase": This phase starts around eight weeks postpartum and continues until the infant is approximately six months old; the phase consists of ten sessions over an 18 week period.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies.

Risks and Discomforts	Benefits to You and Others
1. There is a possibility that the "Mamma Mia" app may not be as good as usual care for enhancing well-being, so one risk is that you use your time on the app and it does not benefit you. 2. There may be some risks that the investigators do not know about yet, so we will let you know of any new findings. 3. Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. 4. The study surveys ask questions that are sensitive in nature and may make you feel uncomfortable. We appreciate your time and effort in completing these questions, so you will receive a gift card upon completing the surveys. The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.	There is some evidence that the "Mamma Mia" app is effective in enhancing well-being during pregnancy and the postpartum period. However, it is unlikely that it will work with everyone, and we cannot promise that it will help you. This study may help the investigators learn things that may help other people in the future. There is no guarantee that you will receive any benefits from being in this study. However, possible benefits include the use of the "Mamma Mia" app. We hope the information learned from this study will provide more information about whether and how the "Mamma Mia" app enhances well-being during pregnancy and the postpartum period. There is no expected impact for the fetus/infant.

WHAT ARE THE COSTS?

You will not be charged for the use of the "Mamma Mia" program or for any study procedures.

We expect that you will continue to receive your usual prenatal and postpartum care throughout the study. You and your insurance plan will need to pay for the costs of your regular prenatal and postpartum care, just as you would if you were getting the usual care for your condition. This includes:

- The costs of study visits that you have during the study
- Your insurance co-pays and deductibles.

We expect that you will be available by phone, email, or text messaging by the study staff throughout this study and that you will use a smartphone or other electronic device to access the "Mamma Mia" app. You will have to continue to pay for your phone or other electronic device that you plan to use to communicate with us during the study.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid $20 by gift card for each completed study survey, and if you complete all scheduled study surveys including the early postpartum survey, you will receive up to $140. If you withdraw before the end of the study, you will be paid for the surveys that you have completed before withdrawing.

If you are participating in other studies at the same time: total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety
- you are found to not be eligible for the study (for example, you are no longer pregnant or you no longer have phone/ email/ text and access to the "Mamma Mia" app)
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services and FDA

In general, we will not give you any individual results from the study. Once the study has been completed, you can access a summary of all of the results of the study and what they mean on our study website.

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

In this study, we will ask you questions about depression symptoms. If you score very high on the depression scale, we will contact you to make sure that you are safe and do not want to hurt yourself. If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know. In addition, we will ask you to provide the names of emergency contacts, and if we are unable to reach you within 48 hours, we will call them to ensure that you are safe.

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent. For example, our study team may gather data from other individuals in other studies and compare findings with this study.

Certificate of Confidentiality

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited.

The researchers may share information about you or your participation in the research project without your consent if there is known child abuse/neglect or harm to yourself or others.

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

OPTIONAL STORAGE FOR FUTURE RESEARCH STUDIES (NON-REGISTRY)

To advance science, it can be helpful for researchers to contact participants later to ask additional or follow-up questions after the completion of this study. We do this by storing your contact information in our password-protected files. This is NOT a registry or repository. Rather, this is a method for us to contact you if we have additional questions about how you are doing. Your data will be protected, but there is always a possibility that information could be accessed by individuals without authorization. There is no limit on the length of time we will store your information. In the future, if you decide that you do not want to be contacted, you can request that your contact information be removed from our files by contacting the principal investigator below.

Permission to Store Contact Information for Future Research Studies

Please check your answer: I agree that my contact information may be stored and used for future research as described above.

YES NO

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

VCU Principal Investigator: Patricia Kinser
Email: kinserpa@vcu.edu
Phone: 804-828-9140
and/or
VCU Study Coordinator: Sara Moyer
Email: moyersw@vcu.edu
Phone: 804-339-1230

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By agreeing to participate, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My agreement indicates that I freely consent to participate in this research study. I may print this consent form for my records.