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Official Title: Responsive e-Health Intervention for Perinatal Depression in Healthcare Settings

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Oregon Research Behavior Interventions Strategies, dba Influents Innovations

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CONSENT FORM

Responsive eHealth Intervention for Perinatal Depression in Healthcare Settings

Principal Investigator: Richard K. Silver, MD

Principal Investigator telephone number: 847-570-2860

Sponsor: National Institute of Mental Health

KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to give your consent to participate in a research study. Participation in this study is voluntary.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why is this research being done?
This research will see if pregnant and postpartum women can get help for depression or anxiety with a program they can use on a computer or a smartphone. For more information, please see the *Why is this study being done?* section below.

How long will I participate?
3 months

What will happen to me during the study?
You will be asked questions about your mood. If you are in the intervention group, you will be given instructions on how to use an online tool on your computer or smartphone. A coach will call you periodically to see how the tool is working for you. Three months later, you will be asked satisfaction questions. If you are in the control group, you will be provided supportive referrals. Three months later, you will be asked satisfaction questions. For more information, please see the *What will happen during the study?* section below.

Will I benefit from the study?
It is possible that you may benefit from taking part in this study; however, there is no guarantee that it will help you. For more information, please *see Are there benefits to taking part in the study?* section below.

Will taking part expose me to risks?
This research is considered no more than minimal risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam. For details and a list of risks you should know about, please see the *What side effects or risks can I expect?* section below.

Will I be paid to participate?
Payment for your time or travel is available if you decide to take part in this study. For more information, please see the Will I be paid for participating? section below.

Will it cost me anything to participate?
There is no cost to you for taking part in this study.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

EXPLANATION OF STUDY:

Introduction: You are being asked to volunteer for this clinical research study because you are a pregnant or postpartum patient who may be experiencing mood symptoms.

This Consent Form gives information about the study that you can talk about with your doctor and/or family. You are being given this information to help your decision. If you have any questions, you can ask the study doctor or staff.

Why is this Study Being Done?

Perinatal depression is the most common complication of childbirth. There are many barriers for mothers who try to seek treatment for their mood, such as child care, time and money. Because of the convenience, more and more people are using their personal devices like phones and computers for medical advice or help. This study will look at whether a program called *MomMoodBooster* is more helpful than being referred for traditional treatment alone.

This study will include a total of 210 patient subjects. Of those subjects, all will be from NorthShore University HealthSystem (NorthShore).

What Will Happen During the Study?

The study coordinator ask you a few questions after which point the coordinator will use our online tool to randomize you to receive either the online tool called MomMoodBooster or referrals for traditional treatment like therapy or a support group. Women assigned to receive MomMoodBooster will then receive a brief description of how they will access and use MomMoodBooster. A welcome email will be sent to you. Emails sent to women who are getting MomMoodBooster will include a link to a website (mommoodbooster.com) where you can create a password and start using MomMoodBooster. You can use the tool for as little or as long as you like at a time and place that is convenient for you – on your phone or computer. If you are receiving referrals, you can seek them when it is convenient for you. You can attend therapy, a psychiatry visit and/or a support group when and where it is convenient for you and as often as you prefer. After three months, you will be asked some questions about using either MomMoodBooster or the referrals for treatment. You will be paid $100 for your time.

During this study, the research team will collect information about you for the purposes of this research.
The information is about your mood and what you may have done to improve your mood. We are asking about this to see whether the tools you were given helped you.

1. A health questionnaire will ask about your mood.
2. A behavior questionnaire will ask about things you did, like "I stayed in bed for too long even though I had things to do."
3. Another questionnaire will ask about negative thoughts.
4. You will be asked about what kind of treatment you used, like just MomMood Booster, and/or a support group.
5. If you used MomMoodBooster, you will be asked how easy or difficult it was to use. The system will tell the study personnel how you used the tool, like number of times, whether you launched a video, etc.

How Long Will I Be In the Study?

3 months.

What Other Choices Do I Have?

You do not have to take part in this study for treatment of your mood. Other treatments include informal support like talking to friends and family, or exercising. You may also choose no further treatment. Your doctor can explain your disease/condition and the good and bad things about each of the options. You are free to talk about your disease/condition and your health with your doctor.

Are There Benefits to Taking Part in the Study?

Taking part in this study may or may not make your health better. Doctors hope that this procedure will be more useful in treating your disease than the usual treatment. However, there is no proof of this. There is the possibility that your health may become worse while you are in this study.

What Side Effects or Risks Can I Expect?

As with women who are not in the study, there are potential risks to not treating your mood, such as worsening symptoms. However, this is a study with minimal risk to you. Should you become upset when answering any study questions, you may access NorthShore's Perinatal Mood and Anxiety Hotline, aka MOMS Hotline for free and confidential support from a licensed mental health professional. As for the information you

disclose in questionnaires, precautions are taken to ensure that the information you provide us stays confidential, such as using a code to identify you instead of your name.

Will My Medical Information Be Kept Private?

Information from this study could be published in journals or presented at meetings. If either of these happens, your name and other personal information will not be used. The researchers running this study will try to keep your personal information private. Your study related information may be looked at by other doctors in this study. Your research file can also be looked at by the NorthShore Institutional Review Board, other medical personnel at NorthShore who are involved in your care, or by the Food and Drug Administration (FDA).

Will my information be used for research in the future?

Information or specimens collected from you for this research study will not be used for future research studies or shared with other researchers for future research.

Protected Health Information (PHI)

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "protected health information (PHI)." In general, under federal law, PHI is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your PHI for research and why they may need to do so.

Your PHI will only be used for the purposes described in this Consent Form. Your authorization for activities described in this section does not have an expiration date.

What protected health information (PHI) will be used?

Information about research procedures, including research office visits, medical tests, procedures, interviews and questionnaires

Who may see, use and share my PHI and why may they need to do so?

- NorthShore research staff involved in this study
- Non-research staff within NorthShore who need this information to do their jobs (such as for treatment, payment (billing) or health care operations)
- The NorthShore IRB board that oversees the research and the NorthShore research quality improvement program
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other US government bodies that oversee or review research)
- The sponsor(s) of this study, and the people or groups it hires to help perform this research

- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- People or groups that we hire to do work for us, such as data storage companies, insurers and lawyers
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

Some people or groups who get your PHI might not have to follow the same privacy rules that we follow. We share your PHI only when we must and we ask anyone who receives it from us to protect your privacy. However, if your information is shared outside NorthShore, we cannot promise that it will remain private.

Do I have the right to withdraw permission for the use of my PHI?
You have the right to withdraw your permission for us to use or share your PHI for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

Once permission is withdrawn, you cannot continue to take part in this study. However, you will not be penalized or lose any benefits to which you are entitled.

Do I have access to my health information?
You have the right to see and get a copy of your PHI that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. However, to protect the study, you will not be able to see some of the study information until after the study is completed. The researchers are not required to release to you research information that is not part of your medical record.

You have the right *not* to sign this form that allows us to use and share your PHI for research; however, if you do not sign it, you cannot take part in this research study.

Will I Be Paid for Participating?

You will be paid a sum of $ 100 for being in this research study. You will be paid at the end of the study. You will be paid by check or, if you are an employee, paid through payroll.

Will There Be Additional Costs?

There is expected to be no additional cost to you from being in this research study. You will still be responsible for all costs that you would normally incur as part of routine care.

What If I Am Injured During the Study?

If you become hurt or sick because of being in this research study, you can get medical treatment at NorthShore. You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. You can ask for more information from the Research Institute of NorthShore.

Health insurance plans (including Medicare) may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Can I Withdraw From the Study?

Your participation in this research study is voluntary. If you decide not to be in this study, you can still get medical care as usual. If you decide to participate now, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

What Are My Rights as a Research Subject?

You may get more information about your rights from the Chairperson of the Institutional Review Board (IRB). You can also call the IRB Coordinators at 224/364-7100. These are the people you should contact about any problems or research-related injuries that happen during the research study.

By participating in this research study you do not waive any rights to which you would normally be entitled.

Will I Be Informed of New Information About the Study?

Any significant new information that may affect your participation will be given to you as soon as it becomes available.

We may learn things about you from the study activities which could be important to your health or to your treatment; however, we will not share this information with you.

Who Can I Call With Questions?

The study doctor and staff will answer any questions you have. If you have additional questions at any time during the study, you may contact the Principal Investigator, Richard K. Silver, MD**,** at telephone: 847-570-2860.

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INDIVIDUAL PROVIDING EXPLANATION:

The procedures and/or investigations described in the above paragraphs have been explained to you by:

Name of Person Explaining Study (Please PRINT)	
Signature of Person Explaining Study	
Date Study Was Explained	

CONSENT TO PARTICIPATE:

I understand that the Principal Investigator and study staff will supervise the study. I have read this consent form or have had it read to me. I understand what will happen if I enroll in this research study. I understand the possible benefits and risks of the study. I have been told about all of my treatment options. I give permission for the research study procedures described in this consent form.

I have reviewed this information with the study doctor and/or staff. I have had enough time to talk about all of my questions and concerns. I willingly consent to be a part of this study. I will receive a signed and dated copy of this Consent Form.

Subject's Name (Please PRINT)	
Subject's Signature	
Date Subject Signed	