Official Title: Randomized Trial of Telehealth Group Intervention to Reduce Perinatal Depressive Symptoms in Diverse Populations

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Consent and Authorization Document

BACKGROUND

You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

Depression and anxiety during and after pregnancy can lead to health problems for the mother and/or baby; it is important to find ways to reduce symptoms. There is little research about how telehealth, such as videoconferencing Intervention (VCI) can support women regardless of where they live. The purpose of this study is to evaluate the effectiveness of using a group-VCI approach to reducing depression and anxiety during and after pregnancy. We want to evaluate this approach among women living in urban and rural areas, as well as among different ethnic backgrounds (Hispanic and North European descent). Using telehealth may allow more women to have access to prevention and treatment without having to find transportation, travel long distances, leave their home, or pay for childcare. This study is being conducted by Gwen Latendresse, Ph.D. CNM at the University of Utah, College of Nursing. This study is funded by the National Institute of Health: National Institute of Nursing Research.

STUDY PROCEDURES

For this study you will be assigned to one of two groups and participate in the study during pregnancy and/or postpartum. You will not be able to choose which group you will be assigned to. In a "randomized trial" people are put in one group or the other by random chance. This means that a computer will decide by chance which group a person is in, not the investigators running the study. All groups will have access to the "videoconference" system (see others by video camera) via computer, electronic tablet, or smartphone and attend weekly 1-hour group sessions for 10 weeks. One of the 2 groups will engage in an intervention called UPLIFT, a program for learning skills to reduce depression and anxiety. Depending on when you start (during pregnancy or after the baby's birth), the other group will engage in a program for learning skills about pregnancy, childbirth, infant feeding, and early parenting, or a program for learning skills about parenting newborns and infants.

Before the group sessions, study staff will meet with you to check your internet connection and an electronic device. You will be provided with instructions and you will be shown how to connect to the videoconference platform. Depending on any technological issues, more than one meeting may be required.
After checking the videoconference system, you will be scheduled for a 30-minute video conference or phone meeting with a facilitator of the group sessions.

During the hour-long weekly group sessions you will engage in the following activities by videoconference:

- Initial orieintation session to get to know each other and the program
- Eight sessions for engaging in the program content

- A final reunion session to reconnect with the group
- A focus group session 6 to 8 weeks after the conclusion of the group sessions to gather participants' feedback. The focus group will only be conducted with a portion of the study participants.

Those who are selected to attend the focus group session will receive $20 gift card for attending.

All of the focus groups and content sessions will be recorded. A random selection of recordings will be transcribed and then destroyed immediately after transcription. Your name or other identifiers will NOT be included on these transcripts.

All participants are asked to complete a questionnaire to measure depression and anxiety 6 times during the study:

- Before starting the 10-weeks of group sessions
- After finishing the 10-weeks of group sessions
- 2 months after finishing the group sessions
- 4 months after finishing the group sessions
- 6 months after finishing the group sessions
- 8 months after finishing the group sessions

The questionnaires will be sent to you by email link, and will take about 15-20 minutes to complete. You will receive a $20 gift card for each questionnaire you complete.

RISKS

The risks of participating in this study are minimal. You may feel upset thinking about or talking about personal information related to depression or anxiety. These risks are similar to those you experience when discussing personal information with others. If you feel upset by this experience, you can tell the researcher, and she will tell you about the resources available to help.

We ask that participants never discuss with others outside of the group, who or what they see, read or hear during the group sessions. However, we cannot guarantee that this won't occur.

BENEFITS

We cannot promise any benefits to you from your being in the study. However, possible benefits may include learning more about your health and your baby's health, both physical and mental. Participation may reduce symptoms of depression and anxiety, and may increase a sence 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. Participation in this study is not a substitute for your routine prenatal, birthing, and/or postpartum care, and 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 Gwen Latendresse, the study doctor at (801)587-9636. If you think you may have been injured from being in this study, please call 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 can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later. You will still receive your current prenatal, birthing, and/or postpartum care, as you choose. Your decision will not affect your relationship with your doctor or midwife, 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 those 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 study participation. Please check your internet and/or telephone plan to identify whether you might have additional charges. If you do not have an unlimited data plan, there may be study funds available to help you with costs during participation. Please ask a study team member about this, if needed.

You are not required to buy an electronic device, but to use what you already have. However, if you do not have access to any type of a device, the study may have a device for loan to you during study participation.

You will receive a $20 gift card of your choice to one of 2 grocery/department stores after completion of the study questionnaires (up to a total of $120, depending on number of surveys completed). You will also receive a $20 gift card if you are selected for and attend a focus group session.

NUMBER OF PARTICIPANTS

We expect to enroll approximately 240 participants at the University of Utah

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.
This is the information we will use and include in our research records:

- Demographic and identifying information like 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, like 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 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.

- 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), who reviews research involving people to make sure the study protects your rights
    - The study sponsor: National Institute of Health: National Institute of Nursing Research

- 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 (for example suicide or serious threats toward the wellbeing of others) we will need to contact the appropriate authorities in order to protect you or the public.

- 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 be part of 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.

CERTIFICATES OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information and documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information and documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others.

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