STUDY TITLE: Project BETTER: Bringing Education Through Technology, Empathic Listening, and Research – A Feasibility Randomized Controlled Trial

VCU INVESTIGATOR: Caitlin E. Martin, M.D., MPH, Assistant Professor

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

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SPONSOR: Virginia Commonwealth University

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

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 take home 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 to not 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.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test a new educational technology-based program and brochure as a supplement to prenatal education from your providers. The program provides education about common challenges that pregnant and parenting women receiving medication for OUD often face. Specifically, it addresses the transition from pregnancy to postpartum, possible neonatal abstinence syndrome (NAS) or neonatal withdrawal syndrome (NOWS), and interactions with child welfare. Your experience and opinion are very important to us. We would like to know what you think and how you feel about our program or brochure.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

If you decide to participate in this study, you will continue to get your medical care with the clinic as normal.

First, during pregnancy you will be asked to complete a brief pre-survey and interview led by an RA (Research Assistant) about your quality of life, functioning, mood, pregnancy history, and substance use.

Then, you will be randomly assigned to either the brochure group or the technology-based program group. Your chances of being assigned to either group are random, like "flipping a coin" to receive either the brochure or technology-based program assignment. You have a 1 in 2 chance of receiving the technology-based program assignment and a 1 in 2 chance of receiving the brochures assignment. In other words, you have an equal chance of being assigned to either of the groups. You and the research team will know which group you are assigned to but we are asking that you do not share that information with your medical providers until you are done with the study.

In the brochure group, you will be asked to review a one-page brochure covering the topics mentioned earlier and have access to additional written information online. In the technology-based program group, you will be asked to complete three 25-minute modules covering those same topics. You will be able to review the

brochure or complete the modules in any order that you choose, and you will complete them at a time that works for you. You will have 3 weeks to complete the modules or review the brochure.

After those 3 weeks and still during pregnancy, (regardless of group assignment) you will complete a brief follow-up survey and RA led interview within 2 weeks. This survey and interview will also include questions about the intervention as well as quality of life, functioning, mood, and substance use.

A study team member will do another check in with you 4 to 8 weeks after you deliver your baby and ask you to complete one final follow-up survey and RA led interview. This survey and interview will include questions about the intervention as well as your baby, quality of life, functioning, mood, and substance use.

Study Visit Schedule:

- Study Visit 1: After you enroll in the study, completion of pre-survey and RA led interview in pregnancy
- Study Intervention Period: 3 weeks to complete the technology-based program or brochure during pregnancy
- Study Visit 2: After the 3-week study intervention period, completion of follow-up survey 1 and RA led interview within 2 weeks during pregnancy
- Study Visit 3: Follow-up survey 2 and RA led interview 4-8 weeks after you have your baby

Your participation in this study will last up to 8 weeks after you deliver your baby. Approximately 30 individuals will participate in this study.

If you decide not to enter this study, you can receive the usual care that you would receive if you were not in the study. You do not have to participate in this study to be treated for substance use.

WHAT ALTERNATIVES ARE AVAILABLE?

You can choose not to participate in the study. A decision not to participate in this study will not affect your care in any way.

WHAT ARE THE RISKS AND BENEFITS OF BEING IN THE STUDY?

There is no guarantee that you will receive any benefits from being in this study. However, possible benefits include gaining additional knowledge to help you prepare for the pregnancy to postpartum transition and take care of your recovery. We hope this study may help the investigators learn things that may help other people in the future.

Few risks are expected by taking part in this study. 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. There is the possibility that you may experience some fatigue and/or discomfort when reviewing the content in the brochure or technology-based program. The study interventions and surveys go over information that is sensitive in nature and may make you feel uncomfortable. However, the content in the brochure and modules is a review of information covered in standard treatment. You may choose to skip any question or content that makes you feel uncomfortable and you can stop study participation at time. Finally, you may be disappointed if you are not assigned to the group you wanted and are not able to access the technology-based program or brochure throughout the study.

WHAT ARE THE COSTS?

You may incur data usage costs while completing the study if you choose to complete it remotely. It is also possible you may incur costs from receiving the survey links via text message, depending on your cellular plan.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

All study participants will earn equal amounts of compensation for their time and efforts for completing research assessments. Study participants will receive a total of $60 for completion of all study components: $20 for completion of the pre-survey and RA led interview (Study visit 1), $20 for completion of follow-up survey 1 and RA led interview (Study visit 2), and $20 for completion of follow-up survey 2 and RA led interview (Study visit 3). Participants will be offered the option to receive a mailed check or cash following the completion of a study visit OR the option to delay individual visit payments in order to receive a subsequent cumulative payment mailed check or cash after completion of multiple completed study visits.

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. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

Payment Schedule:
Study Visit 1: Pre-survey and interview (during pregnancy): $20
Study Visit 2: Follow-up survey 1 and interview (during pregnancy): $20
Study Visit 3: Follow-up survey 2 and interview (during 4-8 weeks postpartum): $20

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. Tell the study staff if you are thinking about stopping or decide to stop. If you leave the study before the final regularly scheduled visit, you will be compensated only for your completed study visits.

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
- 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 according to VCU's policies (i.e. for a minimum of 5-6 years). Any additional information you provide will be stored in a locked location. Your information is only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

You should know, however, that researchers must tell someone if you tell us that you may cause harm to yourself, harm to others, or if child or elder abuse becomes a concern.

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:

- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

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

CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, we will obtain 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, or if the information is required by the Food and Drug Administration (FDA).

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that will identify you as a participant in the research project if you tell us that you may cause harm to yourself, harm to others, or if child or elder abuse becomes a concern.

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

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

If you have any questions, complaints, or concerns about your participation in this research, contact:

Dr. Caitlin E. Martin
Assistant Professor
VCU Department of Obstetrics and Gynecology
1101 East Marshall Street, 11th Floor, Room 11-027 Richmond, VA 23298
Box #980034
Phone # 804-628-7023.

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

If you have general questions about your rights as a participant in this or any other research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.