RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Stress and Feeding: A Pilot Intervention for Mothers and Their Preterm Infants

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SPONSOR: School of Nursing Intermural Grant Program

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 infant.**

This consent form is meant to assist you in thinking about whether or not you and your infant 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 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 or your infant are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is two-fold. First, we will examine how practical and acceptable it is for mothers of preterm infants to participate in Stress And FEeding (SAFE) intervention and collect biological stress measures from mothers and their preterm infant's saliva (spit). The second purpose of this study is to examine changes before and after using the intervention. We think the intervention may reduce stress and improve maternal feeding interaction. This study will allow us to learn more about it.

What will happen if I participate?

After consents are signed, the researcher will show you how to collect your salivary (spit) samples, give you directions, and supplies for sample collection. You will be asked to collect three samples before each data collection visit at the following times: immediately upon awakening, 30-minutes after waking, and before going to bed. Reminder calls/text message will be sent 2-days before the visit to help remind you to collect the samples. For every visit a date and time will be set at your convenience for the next visit.

For the baseline stress visit you will give your three salivary samples you collected the night before to the researcher and you will be asked to fill questionnaires about your mood, stress and your family). We will loan you an Apple device and show you how to use it to access the stress management intervention. You will be asked to listen to the stress management audios a minimum of three times per week for the first 4-weeks and then listen to the 2-5-minute stress management boosters 3-times a week for the

remaining 4-weeks. You are also being asked to fill out a daily log before and after you listen to the audio exercises. You will receive a $5 gift card every week for the 8-weeks if you complete and submit your daily logs. (~ 20-minutes for the visit)

The baseline feeding visit will occur when your baby begins to nipple feed (~33-34 weeks). The researcher will collect the infant's saliva and you will collect your own. You will be video recorded feeding your baby. After the feeding you will be shown how to access the infant videos and you will watch all videos with the researcher. You will again collect your saliva samples and the researcher will collect your infant's. You will be asked to fill out the feeding section of the daily logs in addition to the stress levels and reminded that you will receive $5 each week for the 8-weeks that you complete and submit your logs. You will be asked to watch the infant videos a minimum of 2-3 times before your first practice session. (Visit ~ 60-75-minutes)

At the first practice session the researcher will point out the infant's behaviors and demonstrate strategies to improve the feeding. You will be interviewed you about your feeding beliefs and this will be audio recorded. You will be asked to view all maternal videos 2-3 times before the next session. At the second practice session you will be asked to help the researcher point out maternal and infant behaviors and will suggest strategies to improve maternal feeding. You will be asked to watch any section(s) of the videos 2-3 times before the final session. At the final practice session, you will be asked to point out both maternal and infant feeding behaviors and demonstrate strategies to improve the feeding.

At **8-week and 12-week visit** in the NICU or at home the salivary samples that you collected the day before will be collected. Before the feeding the researcher will collect your infant's salivary samples and you will collect your own. You will be video recorded feeding your infant. After the feeding you will be interviewed about your feeding beliefs and fill out the mood and stress questionnaires. The researcher will again collect salivary samples from your infant and you will collect your own. (Visit ~ 60-75-minutes)

At the **16-week visit** the procedure will be the same except an infant developmental assessment will be completed and you will be asked about your experience in the study (a questionnaire and an interview). (Visit ~ 75-90-minutes)

You will be given $25 after every data collection visit ($125). If the visit happens in the home we will also be collecting growth measures on your infant (weight, length, and head circumference).

Usual care in the NICU does not involve the nurses routinely observing a feeding nor providing feedback to the mother and no stress management strategies are offered. In this study, you will receive usual care, and in addition, you will be asked to do the following things:

1. Fill out forms about your mood, stressors, and family background information
2. Collect your salivary (spit) samples and place in your freezer four times.
3. You will be asked to collect your salivary (spit) samples four time while the researcher collects salivary (spit) samples from your infant 4 times before and after the infant's feeding
4. Listen to audio recorded relaxation exercises a minimum of three times a week for 10 minutes for the first 4-weeks

5. Listen to the 2-5-minute audio recorded booster relaxation exercises a minimum of 3 times a week from weeks 4 through 8.
6. Keep a daily log by recording your stress levels before and after listening to the audio recorded relaxation exercises and document listening time
7. Watch video recorded feedings of mothers and their preterm infants during feeding interactions for four weeks and document viewing time on your daily log
8. Be video recorded feeding your infant
9. Have discussions with the nurse researcher about feeding your infant, which will be audio recorded
10. Provide a 24-hour feeding recall for your infant during the home visits and on the phone prior to the home visits.
11. Complete the final study evaluations, including an audio-recorded interview and survey about your experience during the study

Your participation in this study will last up to 16-weeks. Approximately 15 mothers and 15 infants will participate in this study.

This study might use your samples to sequence all or part of your DNA.

Deoxyribonucleic acid (DNA) is the "blueprint" or "recipe" that gives the body's cells instructions on how to do their jobs. Scientists can use a test called whole genome sequencing to determine the order of all or part of the molecules that make up your DNA, like reading all the letters in a book. Sequencing is usually done to look for changes in the molecules of DNA that may cause health problems.

What alternative treatments or procedures are available?

The only alternative is to not participate

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section.

Risks and Discomforts	Benefits to You and Others
1. There is a risk that you could have problems because of doing the SAFE intervention. Below are some of the most common risks and discomforts: • The most common health risk for using earbuds is hearing damage if the volume is turned up high	1. There is no guarantee that you will receive any benefits from being in this study. However possible benefits include decreasing stress and anxiety, as well as improving sleep and feeding behaviors. We hope the information learned from this study will provide more information about maternal

• Participation in research might involve some loss of privacy. There is a small risk that someone outside the study could see and misuse information about you. • The study questionnaires ask personal questions that are sensitive in nature and may make you feel uncomfortable. • An unlikely but potential risk of using a relaxation technique is relaxation-induced anxiety 2. There may be some risks to you that the investigators do not know about yet, so we will let you know of any new findings.	stress and preterm infant feeding.

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

After you sign the consent, the researcher will show you how to collect your salivary sample and give you directions for sample collection.

Salivary Collection: The day before each study visit you will be asked to collect three saliva samples at the following times: upon awakening, at 30 minutes after-awakening, and at bedtime. You will be given an oral swab to place under your tongue for 1-2 minutes and then place in the storage tube, which you will be asked to label with the date and time. You will be asked to freeze the samples immediately after collection and bring them to the next scheduled study visit.

A time and date will be set for your baseline visit and you will be given the salivary collection kits. A reminder phone call or text message will be sent prior to the baseline data collection visit. This visit should take about 20-minutes.

At the baseline stress visit, in the NICU, you will give the salivary samples you collected the previous day to the researcher and complete the forms about your mood, stressors, sleep, and your family background. You will be provided with an encrypted Apple device and a passcode. The researcher will demonstrate how to access the audio recordings on the device, you will be offered ear buds to help cancel out distracting noise, and your questions answered. You will be instructed to start listening and to keep a daily log of your listening for 8-weeks. You will be given a $5 gift card every week for 8-weeks if you complete and submit your daily logs. You will be asked to access the website and listen to a 10-minute stress management recording a minimum of three days a week for 4-weeks, and then listen to a 2-5-minute stress management booster a minimum of three times a week for the remaining 4-weeks.

You will receive weekly phone calls/text messages to answer any questions, trouble shoot any difficulties, and encourage daily practice and application into your daily life.

When your baby is ready to begin nipple feeding (around 33-34 weeks) a time and date will be set for your baseline feeding visit. Before the feeding the researcher will collect the infant's salivary sample by placing the infant oral swab in the infant's cheek for 1-2 minutes or until the lower third of the swab is saturated and you will collect your own salivary sample. You will feed your infant and the feeding interaction will be video recorded. Thirty-minutes after the feeding, salivary samples will again be collected from you and your infant. While waiting the 30-minutes the researcher will demonstrate how to access the video recordings on the Apple device. You will watch all the videos (~30-minutes) with the researcher and any questions will be answered. You will then be asked to review the infant videos (~12-minutes) 2-3 times before your first practice session. You will be reminded to complete the daily log of your listening and watching for the remainder of the 8-weeks and that you will be given a $5 gift card every week for the 8-week intervention if you complete and submit your daily logs. A time and date will be set for the first practice session and you will be given a $25 gift card. This visit should take about 60-75 minutes.

At the first practice session, in the NICU, the researcher will interview you about your feeding beliefs, and this interview will be audio recorded. While feeding the infant, the researcher will point out the infant's behaviors and demonstrate strategies to improve the feeding. After the feeding, you and the researcher will discuss the feeding, set feeding goals, and schedule a date and time for the second practice session. You will be asked to watch the maternal feeding videos (~12-minutes) a minimum of two to three times before your second practice session.

At the second and third practice sessions, in the NICU, the procedure will be the same except you will point out the infant and maternal behaviors and demonstrate strategies to improve the feeding. After the second practice session you will be asked to watch any section of the video clips (~31 seconds to 6-minutes 16 seconds) a minimum of two to three times a week. You will be reminded that we will give you a call to set-up a day and a time for the next visit. About a week before the 8-week visit a day and time will be set for the visit. Two days before the visit you will receive a reminder phone call/text message about the meeting and asked to collect your three salivary samples.

At 8-weeks, in the NICU or at home, you will give your salivary samples you collected the previous day to the researcher. Before the feeding the researcher will collect the infant's salivary sample and you will collect your own salivary sample. You will feed your infant and the feeding interaction will be video recorded. After the feeding, you will complete the forms about your mood and stressors. You will also be interviewed about your feeding beliefs, and this interview will be audio recorded. If at home the infant's growth measurements will be taken (weight, height, and head circumference) and 24-hour diet recall will be collected. Thirty-minutes after the feeding salivary samples will again be collected from you and your infant. You will be given a $25 gift card. This visit should take about 60-75 minutes.

Around 1-week post-discharge, a researcher will call you to discuss your feeding goals and provide opportunities for problem-solving and you will be audio interviewed about how things have been going since discharge.

A week before every visit you will receive a reminder phone call to confirm the date of the visit. Two days before the visit you will receive a phone call/text message to remind you to collect your samples.

At 12-weeks, in the NICU or at home, you will give the salivary samples you collected the previous day to the researcher. Before the feeding the researcher will collect the infant's salivary sample and you will collect your own salivary sample. You will feed your infant and the feeding interaction will be video recorded. After the feeding, you will complete the forms about your mood and stressors. You will also be interviewed about your feeding beliefs, and this interview will be audio recorded. If at home the infant's growth measurements will be taken (weight, height, and head circumference) and a 24-hour diet recall will be collected. Thirty-minutes after the feeding salivary samples will again be collected from you and your infant. You will be reminded that you will receive a phone call about a week before your next and final visit. You will be given a $25 gift card. This visit should take about 60-75- minutes.

At 16-weeks, in the NICU or at home, you will again give the salivary samples you collected the previous day to the researcher. Before the feeding the researcher will collect the infant's salivary sample and you will collect your own salivary sample. You will feed your infant and the feeding interaction will be video recorded. After the feeding, you will complete the forms about your mood and stressors. You will also be interviewed about your feeding beliefs, and this interview will be audio recorded. If at home the infant's growth measurements will be taken (weight, height, and head circumference), a 24-hour diet recall will be collected, and the infant's developmental assessment will be completed. You will complete two study evaluations. One will be an audio recorded interview asking you about your experience in the study. In the second evaluation you will be asked to rate how useful, helpful, difficult, and accessible you felt the study was for you. Salivary samples will again be collected from you and your infant. At the end of the visit you will be thanked for your participation and you will be given a $25 gift card. This visit should take about 75-90 minutes.

Information about your infant's hospitalization will be collected from your infant's medical record during your participation in the study. Your participation in this study will last for 16-weeks.

WHAT ARE THE 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 decreasing stress and anxiety, as well as improving sleep and feeding behaviors. We hope the information learned from this study will provide more information about maternal stress and preterm infant feeding.

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

Your condition may not get better or may become worse while you are in this study.

Possible Risks Associated with [Study Intervention]

Rare (Less than a 1% chance that this will happen)

- hearing damage from using the earbuds
- using relaxation may cause anxiety

Non-Physical Risks

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. Being video recorded and observed during feeding sessions may make you feel uncomfortable.

Genetic Risks:

If known to employers or insurance companies, the results of genetic tests might affect a person's ability to obtain a job or health or life insurance. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, this legal protection still may not keep someone from trying to discriminate against you in this way

Unknown or Unforeseeable Risks

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.

WHAT ARE THE COSTS?

The sponsor is paying for everything in this study. You will not be charged for any study visits, tests, or procedures.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid $25 by gift card after each data collection visit, and if you complete all scheduled study visits, you will have received a total of $125. You will also be paid $5 by gift card every week for 8-weeks if you complete and submit your daily logs to the researchers, you will have received up to $40. Therefore, if you complete all aspects of the study you will receive a total of $165 in gift cards.

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 infant's health or safety
- you or your infant are found to not be eligible for the study
- the sponsor has stopped the study
- 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

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

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.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

If we suspect child abuse or neglect has occurred, we are required to report this information to authorities.

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value

In the future, identifiers might be removed from the information and samples 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.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

☒ Complete health record	☐ Diagnosis & treatment codes	☒ Discharge summary
☒ History and physical exam	☐ Consultation reports	☒ Progress notes
☒ Laboratory test results	☐ X-ray reports	☐ X-ray films / images
☒ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☐ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	
☒ Information about mental health	☐ Information about sexually transmitted diseases	

☐ Other physical or mental health information (specify):

Who will use or share protected health information about me?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
- Study Sponsor

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at Lisa F. Brown, PhD, RN, 1100 E. Leigh Street, Richmond, VA 23298 and/or Nancy Jallo, PhD, FNP-BC, WHNP-BC, RN, 1100 E. Leigh Street, Richmond, VA 23298

OPTIONAL STORAGE FOR FUTURE RESEARCH STUDIES

To advance science, it is helpful for researchers to share information. They do this by putting data or samples into one or more scientific databases (called registries or repositories), where it is stored along with information from other studies. Researchers can then study the information in other ways and combine information from many studies to learn even more about health and disease.

As part of this study, we would like to keep the information and/or samples that you provide, that contains your likeness in a registry/repository to be available for other research studies in the future. Your information and samples would be stored at VCU by Lisa F. Brown, PhD, RN and could be used for other research studies about any topic. Your data/samples 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/samples.

In the future, if you decide that you don't want to be part of this registry, you can request that your information/samples be removed and destroyed by contacting Lisa F. Brown, PhD, RN. However, information that has already been shared with other researchers will continue to be used.

Permission to Store Data and/or Samples for Future Research Studies

Please circle your answer: I agree that my data and/or samples may be stored and used for future research as described above.

YES NO

Permission to Contact You for Future Research Studies

Please circle your answer: I agree that the researchers may contact me by letter or phone for future research.

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:

Lisa F. Brown, PhD, RN
1100 E. Leigh Street
Richmond, VA 23298
lfbrown2@vcu.edu
804-335-9484
and/or
Nancy Jallo, PhD, FNP-BC, WHNP-BC, RN
1100 E. Leigh Street
Richmond, VA 23298
njallo@vcu.edu
757-846-7510

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 signing this consent form, I have not waived any of the legal rights or benefits to which I and/or my child otherwise would be entitled. My signature indicates that I freely consent to participate and give permission for my child to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Signature Block for Enrolling Child Participants - Parent/Guardian Permission	
_____ Name of Child/Youth Participant	
_____ Name of First Parent/Legal Guardian (Printed) *Study team – verify that this individual is the child's parent or legal guardian.*	
_____ **Required** First Parent/Legal Guardian Signature	_____ Date
_____ **Optional** Second Parent /Legal Guardian's Signature	_____ Date
_____ Name of Person Conducting Parental Permission Discussion (Printed)	
_____ Signature of Person Conducting Parental Permission Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date