University of Pittsburgh
School of Nursing

TITLE: Effect of Antenatal Milk Expression on Breastfeeding Outcomes among Overweight and Obese Women

NCT Number: NCT04258709

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PREPARE Study Key Information

1. Participation in this research study is voluntary…	You are being asked to participate in a research study. Research studies only include people who choose to take part. A study team member will explain the study to you and answer your questions.
2. A summary of the research…	**Purpose:** To determine the effects of prenatal video-based education on maternal postpartum experiences and behaviors **<u>Pregnancy visits: weekly from 37-40 weeks</u>** You will be randomly assigned to one of these groups: **1. Breastfeeding group:** Receive video instruction from a lactation consultant on hand expression of breast milk in pregnancy - Hand expression at home 1-2 times/day until delivery **2. Infant care group:** Watch a series of videos on infant care **<u>Postpartum visits: 2, 6, and 12 weeks; 6 and 12 months</u>** • Remote surveys • One audio interview • Optional mom and baby measurements, collection of breast milk samples
3. Potential risks…	Risks related to participating in this study include risks related to: **Surveys:** Mild discomfort with some questions; *you may choose not to answer these questions* **Hand-expression in pregnancy:** Minor physical discomfort; release of oxytocin, a normal hormone when expressing breast milk, which may lead to some mild tightening of your uterus; *you may stop expressing anytime. You should stop expressing (or not begin) and contact your OB provider if you experience any prolonged or very frequent uterine tightening, bleeding, or a decrease in baby's movements.* **Breach of confidentiality (surveys, text messages, or remote video-based interactions)**; *all of your research records will be de-identified, meaning that your name will not be associated with your responses.*
4. Potential benefits…	It is possible that video-based education may lead to greater confidence about breastfeeding or infant care topics (i.e., sleep, car seat safety, breastfeeding) postpartum.

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Study Name: **PREPARE Study: (PR**enatal Video-Based **E**ducation and Post-**PAR**tum **E**ffects**)**

Principal Investigator: Jill Radtke Demirci, PhD, RN, IBCLC
3500 Victoria Street, Suite 440
Pittsburgh, PA 15261
Phone: 412-648-9236

Study Coordinator: Melissa Glasser, PhD (412-624-6997)

Study Sponsor: National Institutes of Health (NIH)

Why is this research being done?

The purpose of this study is to determine the effects of prenatal infant care and breastfeeding video-based education on maternal postpartum experiences and behaviors.

Who is being asked to take part in this research study?

You and your baby are being asked to be in this research study because you:

- are a healthy first-time mother between 34 and 37 weeks of pregnancy
- are pregnant with one healthy baby
- plan to breastfeed and have no conditions that would preclude breastfeeding
- meet body mass index criteria for the study
- plan to deliver at a hospital where the research team has access to delivery records
- have no health issues requiring delivery before 37 weeks of pregnancy
- have a cell phone with unlimited text plan and a device (e.g., phone, tablet) with video connection capabilities

About 280 pregnant individuals and their 280 infants will take part in this study.

What is involved?

If you agree to take part in this study with your baby, you will be randomized to one of two different video-based education groups: 1) infant care or 2) breastfeeding. Randomized means assigned by chance, like flipping a coin. Neither you nor the study team will choose your group. We will meet with you either in-person or remotely (e.g., Zoom video visits) at 37, 38, 39, and 40 weeks of pregnancy (if you are still pregnant at each of these points) to provide video education. Study contacts will also occur remotely or in-person at 2, 6, and 12 weeks, and 6 and 12 months postpartum. At these contact points in pregnancy and postpartum, you will complete surveys asking about your demographics (e.g., age, education, employment), reproductive history, pregnancy, health, baby's health, birth, infant feeding practices, experiences with discrimination, and feelings about your body. We will also collect information about stress, anxiety, depression, and infant feeding confidence, attitude, and satisfaction. We may also collect anthropometric measurements on you and your baby during pregnancy and postpartum, as well as samples of your breast milk during pregnancy and/or postpartum. Any collected breast milk will be stored at the University of Pittsburgh for futures analyses (TBD). Exact analyses have not yet been decided, but your participation in this research study might include whole

genome sequencing, or your information and bio-specimens (even if identifiable information is removed) may be used for commercial profit; however, you will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or outside agencies may receive. Results of any milk analyses will not be shared with you or any other study participants. The research team will also collect information from your/your baby's medical records related to medical conditions/problems, medications, labor, delivery, and your baby's hospital course and hospital feedings. This information is needed to examine potential issues that may affect your study participation and/or study outcomes.

If you are assigned to the breastfeeding video group, at each prenatal visit we will connect you with video-based breastfeeding education delivered by a remotely-based lactation consultant. If our study staff see you in-person for a study visit, video education will occur on a secure study electronic device (e.g., iPad). If your study visit is remote, video education will occur on your own personal electronic device (e.g., your smartphone) over a HIPAA-compliant remote platform like Zoom. These visits will be facilitated by study personnel and, if visits are remote, both study personnel and lactation consultant will be in separate private areas. The video education will consist of teaching you how to hand-express breast milk. We will ask you to continue expressing milk 1-2 times per day until delivery and document this daily through online diaries. To access these diaries, you will receive a text message alert and reminders. Several studies, including a multicenter, un-blinded study of diabetic women in Australia, have demonstrated the safety and feasibility of hand-expressing milk in pregnancy.

We will provide containers, syringes, and labels for you to collect and freeze milk at home. We will abide by Allegheny County social distancing standards, and may either arrange in-person meetings or contactless porch exchanges for supply drop-offs/pick up of milk samples. You may bring any milk collected in pregnancy (labeled with your name and the date expressed) to the hospital at the time of delivery in the provided cooler, in case your baby needs extra milk after delivery. This milk should be kept sealed in the cooler and stay with you until your baby is born; the cooler will keep your milk cold and safe for baby to consume if it is needed within 36 hours following removal from your home freezer. Instructions for milk storage and use will be affixed to the cooler, along with a 24-hour study number should any questions arise about storing or feeding your milk to your baby. You should alert Labor & Delivery staff to your study participation and whether you have stored milk, should it be needed directly after your baby's birth. Once your baby is born and you are transferred to the postpartum mother/baby unit, notify your nurse about your milk; they will affix your baby's medical label to your milk containers and store your milk in their temperature-log monitored refrigerator. This milk will then require "check out" with two clinical staff prior to use, consistent with hospital policy. Note that milk stored in hospital refrigerators may still only be consumed by your baby within 36 hours of removal from your home freezer. Any unused milk left in hospital refrigerators will be discarded after milk expires or you/your baby are discharged.

If you are assigned to the infant care video group, you will view a video-based infant care education module at each prenatal study visit. If your study visit is in-person, modules will be viewed on a secure study device (e.g., iPad). If your study visit is remote, you will connect via video call if possible with a study staff member and view the education module on your own personal electronic device (e.g., your smartphone). For remote video visits, study staff may share their screen (streaming the education module) over a HIPAA-compliant remote platform like Zoom approved by the University of Pittsburgh. Study staff members will be located in a private

area during video calls. Education modules include infant care and development topics, such as car seat safety.

In either group, you will be asked to complete a survey at the first study visit. At one prenatal visit (if the visit is in-person), you may be weighed and measured (e.g., skinfold and tape measure readings of triceps, hips, bust, etc.) by a trained staff member. After delivery, you will be contacted to complete surveys at 2, 6, and 12 weeks, and 6 and 12 months. You will have the option to complete these surveys remotely via phone or email (or in-person depending on circumstances). If any postpartum visits are in-person, we may also ask to complete additional weight and caliper measurements on you and/or your baby and your baby's length and head circumference at those visits. At postpartum visits, if you are breastfeeding, we may also ask for a small sample of breast milk (up to 10mL) that will be stored at the University of Pittsburgh for future analyses (we can arrange contactless porch pick-ups of milk if needed). Finally, at 6 weeks postpartum, a member of the study staff may invite you to take part in a phone interview lasting about 30 minutes asking for your feedback on the study. If you report that you will not start breastfeeding, have not started breastfeeding, or stop breastfeeding before 6 weeks postpartum, you may be asked to complete an interview before 6 weeks postpartum. Approximately 25% of participants will be contacted for a phone interview, based on variability in participation, demographics, and infant feeding.

What happens if I have a health problem while I am in the study?

If the study team notes any potentially serious health issues during study visits, we will refer you to emergency services, your pediatrician, obstetrician, or primary care medical provider, as appropriate. If you participate in this study, we will place a note in your medical record to alert your obstetrical provider to your participation, with an explanation of study risks and benefits.

Study schedule

BF=breastfeeding group; IC=infant care group

	PREGNANCY			**POSTPARTUM**				
STUDY ACTIVITY	**34-36 wks** *30 m* **($10)**	**37 wks** *10-60 m* **($25)**	**38-40 wks** *10-25 m* **($25/visit)**	**2 wks** *10-25 m* **($50)**	**6 wks** *30-40 m* **($35)**	**12 wks** *10-25 m* **($25)**	**6 mos** *10-25 m* **($25)**	**12 mos** *10-25 m* **($50)**
Consent process	BF; IC							
Surveys	BF; IC			BF; IC	BF; IC	BF; IC	BF; IC	BF; IC
Video education		BF; IC	BF; IC					
Weight/skinfold measures		BF; IC		BF; IC	BF; IC	BF; IC	BF; IC	BF; IC
Provide milk sample		BF	BF	BF; IC	BF; IC	BF; IC	BF; IC	BF; IC
Daily milk expression diary		BF	BF					
Interview about study experience					BF; IC			

Will anyone know that I am taking part in this study?

We are asking permission to collect and store private health information from your and your baby's medical record. This is necessary in order for the researchers to obtain details related to

medical factors that may affect study outcomes. Identifiable medical record information will be made available to members of the research team for the duration of the study data collection period, which may extend beyond your/your baby's participation at 12 months after birth. At any time, you may withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page. If you withdraw authorization to access your/your baby's medical records, you will no longer be permitted to participate in the study, and any information obtained from your/your baby's medical records up to the point of withdraw will continue to be used by the research team.

Other groups may access research documents, which contain your private health information, for the purpose of monitoring the study, including the University of Pittsburgh Research Conduct and Compliance Office, a data safety monitor at the University of Pittsburgh, and the funding agency, the National Institutes of Health. These individuals and groups are highly aware of confidentiality laws. We will protect your privacy and the confidentiality of your records but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, if your personal information is disclosed to others outside UPMC or the University. Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project. For projects involving children, records must be maintained for 5 years past age of majority (age 23 per PA State law) after study participation ends.

What are the possible risks and discomforts of this study?

Remote video visits: Remote prenatal study visits will be conducted via a secure, HIPAA-compliant remote platform administered through the University of Pittsburgh, such as Zoom. These meetings will be hosted by a member of the study staff, and may be attended by a board-certified lactation consultant, for participants in the breastfeeding group. It is unlikely, but possible, that someone outside the study staff could join the meeting and see you. However, we will take the utmost precautions to mitigate this risk by using a secure host/server (e.g., HIPAA-compliant Zoom) and "locking" the session so that no other users may join once the study staff member, participant, and lactation consultant (if applicable) join. No study procedures will begin until after the video session has been locked.

Survey and interviews: Some questions we ask in surveys or interviews are sensitive and may make you uncomfortable. You may decline to answer any questions and still participate in the study. During in-person visits, we will give you the option to complete sensitive areas of questionnaires (e.g., reproductive history) on your own, rather than reading items aloud, and will suggest that anyone other than young, dependent children leave the room prior to administration of these questions. It is also possible, but unlikely, that your survey responses may be visible over the internet. To minimize this risk, we ask that you delete your emailed survey link after completing the survey and empty your computer's "trash" after deletion. It is also possible, but unlikely, that your voice may be identifiable on the audio-recorded interview. We will de-identify all of your research records to minimize potential confidentiality breaches.

Hand expression: Hand expressing milk during pregnancy may cause a brief increase of oxytocin, a hormone in the blood. This may cause some tightenings (mild contractions) in your uterus. Prior research in women with diabetes demonstrated that it is unlikely that expressing will cause any problems, like preterm labor. If you notice any of the following things during or

after expressing, you should stop expressing and contact Magee Emergency Department (**412-641-1000**) or your obstetric provider for advice: a prolonged tightening (lasting more than 1 minute); very frequent tightenings (more than 5 in 10 minutes); any vaginal bleeding; or a decrease in the baby's movements. Please also notify study investigators as soon as possible if you experience any of these problems while hand expressing.

Hand-expressing before or after delivery may cause physical or emotional discomfort (particularly if you are not able to get milk out). You will learn how to hand-express in a way that does not normally cause physical pain. We also stress that some pregnant or postpartum individuals are not able to get any milk out with their hands, particularly in pregnancy, when milk volume is small. There is no evidence to suggest that not seeing or being able to express breast milk in pregnancy is associated with breastfeeding problems or low milk supply. If you are assigned to the breastfeeding group, your participation does involve breast exposure in the presence of a study staff member(s) and lactation consultant over video call. If you are uncomfortable with this, you may decline to participate in the study. You may also elect to stop hand expressing at any point during the study (even during the course of a video call) if you feel uncomfortable.

Breast milk storage (breastfeeding group only): While very unlikely, it is possible that milk stored at the hospital (when brought in at the time of the birth hospitalization) could be stored at the incorrect temperature, or that the wrong breast milk sample is given when requested for a feeding. These risks are anticipated to be no greater than if you were storing milk that you pumped/expressed at the hospital after your baby was born.

Text message interactions: Text messages interactions through the study or with study staff are not encrypted or secure during their transmission, and therefore, interception is possible.

Collection and storage of private health information and samples: There is always a risk of breach of confidentiality when you participate in a study, meaning someone not on the study team sees information about you. We take many steps to prevent this from happening, such as locking paper files, and using an ID number instead of your name wherever we can. You may be uncomfortable being weighed or measured by study staff or providing milk samples. You may decline to be weighed and measured and/or decline to provide your breast milk samples and still participate in the study.

Risk to infant: The weight and length measurements of your baby are done by trained study staff and are the same as completed in a pediatrician's office with near zero risk of harm. You can ask for these not to be done and still be in the study.

Will I benefit from taking part in this study?

There is no guaranteed direct benefit to you for participating in this study, but it is possible that the video-based education during pregnancy may lead to greater confidence and knowledge in how to care for your baby or breastfeed. Any milk expressed and stored in pregnancy may also be used after delivery if needed instead of formula. Your participation may help us understand more about what types of prenatal interventions benefit first-time mothers.

Will you maintain my privacy?

We will make every attempt to protect your privacy and the confidentiality of your records; however, we cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University. Hard copies of forms will be stored in locked file cabinets in locked rooms at the University of Pittsburgh. The Principal Investigator has responsibility for control over this storage area. Computer text and audio files will be password-protected and user-restricted. A study number, rather than your name, will be used on all forms, files, and milk samples with one exception. We will keep a single password-protected, user-restricted computer file linking your study number with your name. Electronic and hard-copy study materials will be kept for an indefinite period. The interview at 6 weeks post-birth will be transcribed without identifiers (i.e., your name, your baby's name), so we can analyze it for commonalities between participants. Both the original audio recording and the transcript will be stored/labeled with your study number rather than your name. You will not be identified by name in any publication or presentation of research results. The information or biological samples collected in this study may be used by other investigators or repositories conducting other research after any information that might link you or your baby to the study information has been removed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers may not disclose or use information, documents, or biospecimens 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, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research EXCEPT under the following circumstances: 1) 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; please note that Pennsylvania law requires reporting of witnessed or suspected child abuse, and as such, any information pertinent to this collected about you/your child through your study participation may be released to the appropriate authorities); 2) if you have consented to the disclosure, including for your medical treatment; or 3) if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Will I be paid for participating in this study?

You will receive a University of Pittsburgh reloadable debit card, which we will reload as you complete study activities. You will receive $10 at the baseline visit, $25 at each of the 37-40 week visits, $50 at 2 weeks postpartum, $25 at each of the 6 week, 12 week, and 6 month survey, and $50 at the 12 month visit. You may also receive $25 for completing final study measures, even if you discontinue breastfeeding. Finally, you may receive $10 if you partake in a phone interview at 6 weeks postpartum (or sooner, if you discontinue breastfeeding prior to this point). You can receive up to $320 for study participation. You will also receive reimbursement for parking at Magee-Womens Hospital or bus fare for in-person study visits. There will be no costs to you or your insurance provider for being in this study.

Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the University of Pittsburgh Accounting Office. All compensation is taxable income to the participant regardless of the amount. If you receive $600 or more in a calendar year from one organization, that organization is required by law to file a

Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

Is my participation in the study voluntary?

Yes! Your/your baby's participation in this study is completely voluntary. You may refuse to participate or stop participating at any time, even after signing this form. Your/your baby's medical care will not be affected by study participation. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

If I agree to take part in the study, can I be removed from the study without my consent?

Removal from the study could occur if you are unable to schedule study visits. If you decline to take part in the assigned intervention, you may not receive compensation for the study visit during which the intervention was to be delivered but you may remain in the study to complete surveys and other measures (e.g., body measurements). If you stop breastfeeding or decide not to begin, your study participation may be discontinued after completion of final study measures/assessments. You may supplement with formula and continue to participate in the study. If you experience problems with milk expression (e.g., any instance of prolonged uterine tightening >1 min, frequent uterine tightening >5 times in 10 mins, vaginal bleeding, reduction in fetal movement during or directly after hand expression), you can remain in the study, but you should not continue or resume hand expression (and we will discontinue study visits where hand expression is taught/reinforced). These criteria will be reassessed at each prenatal study visit. If you or your baby develop a serious health issue during the course of the study, whether you may continue hand expression will be evaluated on a case-by-case basis; you may still remain in the study completing surveys and other measures, however.

How do I get more information? If you have questions about your participation in this study, contact the Principal Investigator, Jill Demirci, at the phone number listed on this form. If you have any questions about your rights as a research subject, contact the Human Subject Protection Advocate, IRB Office (1-866-212-2668). You will receive a copy of this consent form.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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.

OPTIONAL CONSENT FOR GENOMIC DATA ANALYSES OF BREAST MILK SAMPLES

We are seeking your consent for possible future analyses of your breast milk. This may involve genetic research, looking at things like your DNA or other parts of your genes, including genomic/phenotypic analyses of your provided breast milk samples. If you do not choose to give permission for DNA/genomic/phenotypic analyses to be performed on your provided breast milk samples, you are still eligible to participate in the rest of the study outlined above. The analysis would likely not be useful in your/your baby's clinical care, and you will not be informed of results.

Your research data, your samples, and genetic/phenotypic data generated from your samples may be shared broadly with other researchers and/or with national/federal repositories; this information will be shared without identifiable information (e.g., your name, birthdate, your baby's name, etc.). The research data/samples may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

In addition, there is a new Federal law, called the Genetic Information Nondiscrimination Act (GINA), that generally makes it illegal for health insurance companies and group health plans to use genetic information in making decisions regarding your eligibility or premiums. GINA also makes it illegal for employers with 15 or more employees to use your genetic information when making decisions regarding hiring, promoting, firing, or setting the terms of employment. This new Federal law does not protect you against genetic discrimination by companies that sell life, disability, or long-term care insurance.

☐ **YES**, I give permission for my breast milk samples to be analyzed for genomic/phenotypic information and shared with other researchers.

OR

☐ **NO,** I do NOT give permission for my breast milk samples to be analyzed for genomic/phenotypic information or shared with other researchers.

Participant Signature: _____ Date: _____

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-888-212-2668).

By signing this form, I agree to participate and have my baby participate in this research study and share our medical record information. I understand that, as a minor (age less than 18 years), my baby is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study. I may request via writing, email, or telephone call withdrawal from the study. I understand that all de-identified data and milk samples will be retained should I chose to withdraw from the study.

A copy of this consent form will be given to me.

For study-related business (e.g., answering questions, scheduling appointments), I give permission for researchers contact me via: *[check all you feel comfortable with]*

□ Telephone call
□ Email
□ Text message

_____	_____	_____
Participant Name	Participant Signature	Date

_____
Infant Last Name and Sex (if known)

Participant cell phone number and email address: _____

_____

CERTIFICATION OF INFORMED CONSENT

I certify that I have carefully explained the nature and purpose of this research study to the above named individual(s) and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date