Consent Form for Participation in a Research Study

UCONN
UNIVERSITY OF CONNECTICUT

Principal Investigator: Ruth Lucas, PhD, RN-C, CLS
Study Title: Promoting Self-Management of Breast and Nipple Pain in Breastfeeding Women
Sponsor: National Institutes of Health, National Institute of Nursing Research

Introduction

You and your baby are invited to participate in a research study involving mothers and their full term babies (>37 weeks at birth) to learn about how new mothers maintain their breastfeeding goals. This study is examining the many factors that may influence nipple and breast pain with breastfeeding and the reasons mothers may stop breastfeeding their newborn.

Research studies include only people who voluntarily choose to participate. This consent form will provide information for you to decide whether or not you and your baby will participate in the study. Please read this consent form carefully and take your time to make your decision. Please feel free to ask questions regarding the purpose of the research, the tasks you will be asked to perform, the possible risks and benefits, you and your baby's rights as research subjects, and anything about the research or this form that is unclear to you. Dr. Ruth Lucas will discuss this consent form with you and be obligated to answer any questions you may have. Then, you can decide if you and your baby want to be in the study or not. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Dr. Lucas is the primary investigator conducting the study. If you decide to participate, you will be asked to sign this form for you and your baby and it will be a record of you and your baby's agreement to participate.

This consent form may contain words that you do not understand. Please ask the study staff to explain any words that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Why is this study being done?

The purpose of this research study is to evaluate the feasibility of a self-management intervention on breastfeeding pain and the influence of psychosocial, sensory and genetic factors on breastfeeding outcomes.

What are the study procedures? What will my baby and I be asked to do?

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

Approximately 80 participants between the ages of 18-45 years will be enrolled in this study at Manchester Memorial Hospital and UCONN Health Center (UCHC) in Farmington. Your baby may not meet criteria to be part of the study if your baby was born 2 weeks before their due date (< 37 weeks gestational age), and has been diagnosed with a congenital anomaly.

In this study you will be asked to complete questionnaires, undergo a sensory assessment, provide a buccal (saliva) sample, and complete a breastfeeding log. During the first study visit, Dr. Lucas or a trained research assistant will come to the hospital to complete the consent form, questionnaires, sensory testing, and collect buccal samples. Study participation after the initial visit will be completed through your own personal device, either a computer/tablet/smartphone, and by telephone consult with a study team member. The first study visit in the hospital will take approximately 45-60 minutes to complete. Study participation afterwards will take 5-30 minutes depending on the task. After the initial visit you will be randomly assigned to either a the intervention group or the usual care group.
If you are in the first group, you will be asked to complete multiple daily log entries of breastfeeding self-monitoring and watch video modules on breastfeeding pain self-management. Daily entries will be completed 6 times/day for the first 2 weeks, then once / day for the remaining 4 weeks. Log entries take 2-5 mins to complete and will ask about breastfeeding patterns at each feeding. At the end of weeks 1, 2 and 6, you will also be asked to complete some questionnaires at home, which will take about 20 mins to complete. Another group will receive the usual care and be asked to complete log entries at weeks 1,2 and 6. At the end of weeks 1, 2 and 6, you will also complete some questionnaires at home which will take about 20 mins to complete. All log entries and video modules will be made available to you through a web-based email link to REDCap, a secure website used to develop the surveys and collect information. You will receive up to 2 reminder emails per questionnaire. If you fail to complete all study data collection points in a timely manner, the study investigator may exclude you from the study.

The study questionnaires ask questions about your breast and nipple pain and how it is affecting your mood, functional status, level of stress, and breastfeeding experience. Examples of the questions that will be asked include rating your pain "at its worst in the last 24 hours", "at its least in the last 24 hours", and "on average". The sensory assessment will involve the application of different stimuli, such as heat, cold, and vibration, to the surface of your skin on your arm. A research team member who is trained to perform the sensory test will remain in the room with you. Sharp and dull sensations will be assessed by applying a nylon filament to the surface of your skin. You will be asked to identify whether the sensation is sharp or dull in response to having the nylon filament against the surface of your skin. A pressure probe will be applied to the surface of your skin to assess pressure sensation, and you will be asked to rate the level of pain in response to the amount of pressure applied. To assess sensation to vibration, a tuning fork will be applied to the surface of your skin and you will be asked to rate the level of pain.

In order to participate in the study, you must be willing to provide a buccal swab at the initial visit. The cheek swab sample for the study will be used to measure genetic factors that are thought to influence pain sensitivity. The genes being evaluated in this study do not have any diagnostic or clinical value, therefore the results of these tests will not be shared you. All samples will be labeled with a unique study identification number and taken to the laboratory in

the School of Nursing in Storrs or to the laboratory at UConn Health. Samples will be stored in the School of Nursing or at UConn Health until further processing. Your samples will be de-identified, meaning they will not be linked with any of your contact information, and will be maintained in the Center's biobank in the School of Nursing indefinitely. Other researchers who may want to perform tests on the samples that you've provided must request approval from the PI and the IRB.

What other options are there?

An alternative is to not participate in this study.

What are the risks or inconveniences of the study?

The study requires 1 visit from a study team member that will be approximately 45-60 mins in duration, which may be inconvenient. In addition, questionnaire completion at home will take 10 minutes to complete and log entries may also take 5 minutes to complete, which may also be inconvenient. Looking at a computer/tablet/cellphone screen for a prolonged period of time may cause eye strain. Additional time to complete the consultation phone calls with the study team may also be inconvenient. Sometimes talking about the symptoms that you experience may cause people to become upset. Several questions will ask about how the pain is affecting your mood and functional status. You may be asked about any drug use or medications that you are taking. You do not have to answer questions that make you feel uncomfortable. If you become upset, the study staff will give you names of counselors to contact so you can get help in dealing with these issues.

Sensory assessment takes about 15 minutes to complete. An experienced research staff member will perform the assessment. During sensory testing, you will be free to move away from the stimulus or to stop testing at any time. The nylon filaments used to assess dull sensation have a blunt tip that allows indentation of the skin without causing a puncture. To minimize the potential for tissue injury during sharp sensation assessment, the filament will be applied with just enough force to cause a pressure sensation.

Having your cheek swabbed may result in slight irritation in your mouth.. Only experienced nursing and research staff will assist with these procedures to minimize any risk.

What are the benefits of the study?

Regardless of what group you are assigned, you will receive educational information about breastfeeding. It is possible that you will not perceive any benefits from participating in this study. However, results from your participation may benefit future patients through a better understanding of how different factors affect breast pain and compliance with breastfeeding in the first few weeks after delivery.

Will I receive payment for participation? Are there costs to participate?

You will receive a $25.00 Target gift card after the completion of the first study visit and a $25.00 Target e-gift card at the completion of Weeks 1, 2, and 6. You will receive a study completion bonus of $25 if you complete all data collection points. You may receive a total of $125 in gift cards if you participate in the entire study.

There are no costs for participating in this study other than the time you will spend in completing the online questionnaires, logs, and interacting with study staff.

How will my baby's and my personal information be protected?

Potentially identifiable information about you and your baby will consist of names, dates of birth and contact information in order to continue to support you during the study. All personal identifying information will be kept in password-protected files and these files will be deleted at the end of the study. Data is being collected for research purposes only. The data collected as a part of this study will have a unique study identifier number (SID#) composed of random numbers, not names, and will be stored separately from the consent form in a locked research area. Any paper questionnaires will be kept in a locked file cabinet for 3-years after the study ends and will be destroyed at that time. Buccal samples and breastmilk specimens will be labeled with ID numbers and stored in a secured research laboratory until it is processed. Buccal and breastmilk samples will be transported and processed at UConn Health.

The data that you provide will have all identifying information removed so that it can be placed in a database maintained by the Center for Accelerating Precision Pain Self-Management (CAPPS-M) at the University of Connecticut School of Nursing (UConn SON). The purpose of the CAPPS-M is to advance theory-based symptom SM interventions, with a focus on pain, and improve pain self-management and health outcomes in diverse populations with acute and chronic pain. A major goal of the CAPPS-M will be building and maintaining a database of de-identified data that includes common data elements (the same measures) across pilot studies so that we can generate a deeper understanding of differences in pain sensitivity between pain types (i.e. low back pain versus abdominal pain) and associated changes in expression of pain sensitivity genes. A component of participating in this pilot study will include having your data de-identified, meaning that we will remove any data that could be used to identify individual participants involved in the study, and transferred to a database that will be maintained by the Center. Once the decision is made to allow data for use to the Center, that permission may not be revoked because it will be de-identified. The de-identified data will be transferred to an NIH-maintained database using a global unique identifier, a set of random alpha-numeric characters that are not generated from personally identifiable information. The global unique identifier generation complies with HIPPA regulations for the protection of personally identifiable information.

You will not benefit directly from having your data included in the de-identified Center or NIH database. However, you may benefit by knowing that you are contributing to scientific knowledge regarding the characterization of pain sensitivity across different pain conditions and associated psychological and genetic factors that may influence pain, which may assist clinicians in their ability to identify of the source of pain.

All source of written data will be stored in a secured, locked study-designated office in the School of Nursing. Electronic data will be collected and stored on REDCap and fire-wall protected servers with access via computers that are password-protected and kept in locked buildings. Access to all data will be limited to only Dr. Lucas and study staff on an as-needed basis. Information provided will remain confidential and not be disclosed to anyone unaffiliated with UConn or UCHC without consent of the participant, except as required by law or regulation. No information will be used in subsequent publications that would identify individual subjects.

The main risk for participating in this study is confidentiality. We will use a standard process across all pilot studies to protect participant confidentiality including using assigned randomly-derived subject study numbers that will be used to track all data and specimens. All data analyses performed by the Center will only include de-identified data. No personal identifiable health information will be maintained in the Center database.

Dr. Lucas and her study team will maintain high regards of you and your baby's confidentially as participants in the study. However, if you screen positive for post-partum depression or the PI or study team is concerned for the safety and wellbeing of yourself we will advise you to contact your provider. If the PI or study team is concerned for the safety and wellbeing of yourself, we will encourage you to seek professional support or refer to regional psychological hotline. In addition, if during the course of this research study, a UConn employee suspects that a minor (under the age of 18) has been abused, neglected, or placed at imminent risk of serious harm, it will be reported directly to the Department of Children and Families (DCF) or a law enforcement agency. We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality.

You should also know that the UConn Institutional Review Board (IRB) and Research Compliance Services may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

What happens if I am injured or sick because I took part in the study?

In the event you or your baby becomes sick or injured during the course of the research study, immediately notify the principal investigator or a member of the research team. If you require medical care for such sickness or injury, your care will be billed to you or to your insurance company in the same manner as your other medical needs are addressed.

If, however, you believe that your illness or injury directly resulted from the research procedures of this study, you may be eligible to file a claim with the State of Connecticut Office of Claims Commissioner. For a description of this process, contact Research Compliance Services at the University of Connecticut at 860-486-8802.

Can I stop being in the study and what are my rights?

You and your baby do not have to be in this study if you do not want to participate. Even if you give permission for you and your baby to be in the study, you may withdraw you and your baby at any time when you change your mind. There are no penalties or consequences of any kind if you decide that you do not want you and your baby to participate.

You will be notified of all significant new findings during the course of the study that may affect your willingness to allow you and your baby to continue.

If you and your baby miss three or more appointments, and do not set up a new appointment, we will withdraw you from the study.

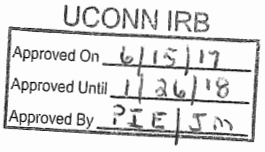
Whom do I contact if I have questions about the study?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have questions about this study or if you have a research-related problem, you may contact the principal investigator, Dr. Ruth Lucas at 860-486-4918. If you have any questions concerning you and your baby's rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.

Documentation of Consent:

I have read this form and decided that I will give consent for my baby and I to participate in the project as described above. Its general purposes, the particulars of my baby's and my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw my baby and myself from the study at any time. I have received a copy of the Genetic Information Non-Discrimination Act (GINA) handout. My signature also indicates that I have received a copy of this consent form.

_____	_____	_____
Participant Signature:	Print Name:	Date:
_____	_____	_____
Signature of Person Obtaining Consent	Print Name:	Date:



Permission Form for Participation in a Research Study

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Parent Copy

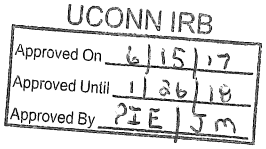
Principal Investigator: Ruth Lucas, PhD, RN-C, CLS

Study Title: Promoting Self-Management of Breast and Nipple Pain in Breastfeeding Women

Documentation of Consent:

I have read this form and decided that I will give permission for my baby and I to participate in the study described above. Its general purposes, the particulars of my baby's and my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw my baby and I at any time. My signature also indicates that I have received a copy of this parental permission form.

Participant Signature:	Print Name:	Date:
Signature of Person	Print Name:	Date:



If you are interested in participating please ask for

Heather Evans or **Heather DeLuca**

or call **860-486-0592**

Congratulations on the birth of your baby!!!

Do you plan on breastfeeding your baby?

Breastfeeding is very important for your baby's health and growth

Participation in the 6-week study includes completing

-Questionnaires

-Sensory testing

- Video Modules

-Daily Feeding Log

-Phone Consultation

-Saliva sample collection

You may receive compensation for your participation

You may be eligible for this study if you:

- Are between 18-45 yrs of age
- Intend to breastfeed your baby for 6 weeks
- Have daily access to a computer
- Your baby was within 2 weeks of due date
- You and your baby had no complications