Forsyth MEDICAL CENTER
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WAKE FOREST UNIVERSITY
HEALTH SCIENCES

Lactation Education Study in Mothers of Very Low Birth Weight Infants

Informed Consent Form to Participate in Research
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Introduction

You and your infant are being invited to participate in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You and your infant are being asked to participate in this study because you delivered prematurely and you are expressing breast milk for your premature infant. Participation is voluntary. Please take your time in making your decision as to whether or not wish to participate or wish to have your infant participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

Why Is This Study Being Done?

Mothers' breast milk protects infants against serious infections during the first months of life and is preferred by doctors over infant formula for infant feeding. Most mothers at the Sara Lee Center for Women's Health begin pumping breast milk for their premature infants. However, the amount of milk mothers produce can decrease over time and may not be enough for infant feedings during their hospitalization. This seems to be related, to some extent, to mothers' understanding of the breast milk pumping instructions they receive after delivery. It is unknown which methods of instruction are most effective at helping mothers understand the breast milk expression instructions. Mothers have told us that they have difficulty remembering the information they receive about pumping and they say it is because they don't feel well after delivery, they don't have enough privacy in the hospital, and they are worried about their babies.

Currently, mothers receive verbal and written instructions during their hospital stay and in preparation for discharge from the hospital. Mothers also have the opportunity to view an instructional digital video disc (DVD) in their hospital room prior to discharge. It is unclear how many mothers are able to benefit from these methods of instruction.

The purpose of this research study is to evaluate the effectiveness of providing an instructional DVD for home viewing. The effectiveness of providing this will be

evaluated by measuring the maternal breast milk portion of infant feedings during baby's hospitalization, a questionnaire to measure knowledge of breast milk expression, and a questionnaire on knowledge of breast milk expression.

How Many People Will Take Part in the Study?

We plan to enroll 40 mothers and their very low birth weight (< 3 pounds, 5 ounces) babies. This study will be conducted at Forsyth Medical Center.

What Is Involved in the Study?

Enrollment

If your baby's birth weight was less than 3 pounds, 5 ounces, you are expressing breast milk, are 18 years or older, and speak and understand English you may qualify to participate in this research study.

Before any study-related activities occur, you will be asked to read and sign this document giving consent for you and your child to participate. You will be given a copy of this consent form after signing.

If you decide to participate and give permission for your baby to participate, you will receive either

- A breast milk expression instructional DVD for viewing at home **OR**
- Similar breast milk expression instructions in written form

The format for breast milk expression instructions that you receive will be determined from a random table (as in the flipping of a coin). This is done so that a fair evaluation of results can be made.

You will be given a questionnaire which will ask you questions about how useful these instructional materials were for you.

Study Procedures

Information about your pregnancy and delivery will be collected from your medical record. During your baby's neonatal intensive care unit hospitalization your baby's health information and the type of feedings will be recorded by nurses each day. The study team will collect this information for the study. The following information will be recorded:

1. Your race, age, delivery type, marital status, Medicaid and WIC participation, number of years of education, and number of children you have.
2. Your baby's birth history information such as birth weight and gestational age, daily weights, and the amount of maternal breast milk or other feedings given.
3. You will be asked to complete a short questionnaire to measure your knowledge of common health words.

4. Knowledge questionnaire. This 20 item questionnaire will measure knowledge of breast milk expression instructions. You will be asked to complete this questionnaire before you are discharged from the hospital and again before your baby is discharged from the hospital.
5. Instructional format questionnaire. This questionnaire will be given to you to complete about one month after your delivery. If your infant is discharged prior to one month we will collect it at the time of hospital discharge. If we miss you we will call you to ask the questions over the phone. If we can not reach you by phone we will mail it to you with a stamped, addressed envelop. We will ask you to complete it and mail it back to us.

How Long Will I and My Baby Be in the Study?

You will be in the study until the DVD viewing log and questionnaire are collected which will be around one month after delivery. Feeding data will be collected from your baby's medical record until s/he is discharged to home or transferred to another hospital. You can stop participating at any time.

What Are the Risks of the Study?

There are no risks involved in participating in this study. Mothers will receive instructional materials on breast milk expression regardless of participation in the study. Verbal and written instructions are given to all mothers prior to hospital discharge. The breast milk expression DVD is available to all mothers for viewing in their hospital room or in the NICU.

Unforeseen risks?

No risks are expected as a result of participating in this study. However, there may be unforeseen risks to participation that we have not considered.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Are There Benefits to Taking Part in the Study?

You may receive additional breast milk expression instructions by participating in this study which may help you provide breast milk for your baby. However, there is no guarantee that you or your infant will benefit from participation in this study.

What Other Choices Are There?

You do not have to be in this study to receive breast milk expression instructions. The alternative to participation in this study is receiving the instructions that all mothers of premature infants at Forsyth Medical Center receive after delivery and viewing the instructional DVD in your hospital room while you are still a patient or in the NICU after you are discharged from the hospital.

What about the Use, Disclosure and Confidentiality of Health Information?

By taking part in this research study, your personal health information, as well as information that directly identify you, may be used and disclosed. Information that identifies you includes, but is not limited to, such things as your name, address, telephone number, and date of birth.

Your personal health information includes all information about you which is collected or created during the study for research purposes. It also includes your personal health information that is related to this study and that is maintained in your medical records at this institution and at other places such as other hospitals and clinics where you may have received medical care. Examples of your personal health information include your health history, how you respond to study activities, and information from study visits, phone calls, and questionnaires.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new instructional materials. Records of your baby's participation in this study will be held confidential.

Some of the people that may receive and use your health information are the principal investigator and project manager; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Forsyth Medical Center; and representatives from government agencies such as the Department of Health and Human Services (DHHS).

Some of these people and agencies may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study.

When you sign this consent and authorization form you authorize or give permission for the use of your health information as described in the consent form. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

[redacted]

If you withdraw your authorization you will not be able to be in this study. If you withdraw your authorization, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. This would be done if it were necessary for the research to be reliable. You will not have access to your health information that is included in the research study records until the end of the study.

Reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and Forsyth Medical Center. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study. This authorization is valid for six years or five years after the completion of the study, whichever is longer.

What Are the Costs?

There are no costs to you for taking part in this study. The DVD will be provided at no charge to you or your insurance company. However, you or your insurance company will be responsible for other costs incurred in your infant's care, since that care will not differ from care usually provided to premature infants.

Will You Be Paid for Participating?

You will receive a music lullaby DVD to compensate you for the time you spend in the study.

The findings from this research may result in the future development of instructional materials that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

Who is Funding this Study?

This study is being funded by the Forsyth Medical Center Foundation. The sponsor is providing money or other support to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the instructional DVD being studied.

What Happens if You Experience an Injury or Illness as a Result of Participating in this Study?

Expenses caused by negligence or misconduct of any person in the employment of Wake Forest University Health Sciences will be covered by Wake Forest University Health Sciences.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, or injury you should call [redacted] after 5

pm call [redacted]

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study if your baby is transferred to another hospital prior to going home.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, you should contact the Chairman of the IRB at [redacted]

You will be given a signed copy of this consent form.

Signatures

I agree to take part in this study and to allow my infant to participate in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

_____
Your Baby's Name/(Printed)

_____
Mother's Name/(Printed)

_____ _____
Signature of Mother Date

_____ _____
Person Obtaining Consent Date