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STUDY TITLE: Nurse-administered Touch and Biobehavioral Stress Responses of Very Preterm Infants (NAT-BIO Study)

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

STUDY TITLE: Pilot Study of Nurse-administered Touch and Biobehavioral Stress Responses of Preterm Infants (Pilot NAT-BIO Study)

PRINCIPAL INVESTIGATOR: Leif Nelin, MD
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CONTACT TELEPHONE NUMBER: 614-349-8788 (24 hours a day, 7 days a week)

STUDY SPONSOR: N/A

SUBJECT'S NAME: _____ DATE OF BIRTH: _____

Key Information About This Study

The following is a short summary of this study to help you decide whether or not to participate. More detailed information follows later in this form.

The purpose of this study is to determine how a touch intervention from nurses affects preterm infants' responses to nursing care. We will compare babies' responses to routine care to babies' responses to care when nurses provide a touch intervention. This study will help us learn if a touch intervention helps babies during nursing care.

Study participation: This study consists of 2 observations of nursing care and a developmental assessment. During the 2 observed episodes of nursing care, we will collect information about how your baby responds to routine nursing care and how your baby responds to nursing care when nurses provide a comforting touch intervention at 3 specific points during care. We will take small amounts of saliva before and after nursing care using a medical sponge. We will also measure how your baby responds to care using monitoring patches on your baby's skin and by watching your baby's behaviors. We will collect information from you and from your baby's medical chart. When your baby reaches approximately 35 weeks, we will perform a developmental assessment.

Study visits: We will observe one episode of nursing care on 2 separate days to collect information about your baby's responses. Your baby will participate in the study for about 6 hours each day. The total time for the observations is 24-48 hours. The developmental assessment takes 20-30 minutes to complete. See a more detailed discussion later in this form.

The main risk(s) of the study: The main risk in this study is skin redness from the monitoring patches. Other risks are listed later in this form.

Benefits: Your baby may be comforted during the touches, but we cannot guarantee this. We hope to learn information that will help others.

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If you are interested in learning more about this study, please continue reading below.

1) INTRODUCTION

We invite you to be in this research study. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. By signing this form, you agree for your baby to be in this study. If you do not want your baby to be in this study, all regular and standard medical care will still be available to your baby here at Nationwide Children's Hospital and The Ohio State University. Participation is voluntary. You can leave this study at any time.

You will be given a signed and dated copy of the consent form.

2) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at Nationwide Children's Hospital (NCH) and The Ohio State University (OSU). We hope to enroll up 20 babies. Babies will be enrolled from the NCH neonatal intensive care units (NICUs).

3) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

Babies in the NICU usually receive nursing care or "cares" every 3 or 4 hours. During this time, your baby's nurse provides all the care your baby needs to be healthy. This includes starting your baby's tube feeding and changing your baby's diaper and other care activities. During this study, we will watch 2 episodes of nursing care and collect information about how your baby responds. During one of the observed episodes of nursing care, your baby will receive routine care. There are no changes to this care from what your baby usually receives. During the other observed episode of nursing care, your baby's nurse will provide a comforting touch intervention. Other than this touch, there will be no changes to nursing care. The nursing care that your baby receives during this study will be determined by his/her medical doctors and nurses. However, we ask that only the nurse provide your baby's care during the 2 observations. If other caregivers such as parents or therapists help with the cares, we will not be able to tell if the comforting touch intervention was helpful to your baby.

Your baby's nurse will provide the touch intervention during one of 2 observed "cares". We will observe 2 "cares" and collect information to learn how babies respond to care with and without the touch intervention. We will observe these cares after your baby is at least 10 days old. These observations will occur between 10 am in the morning and 1 pm in the afternoon. We will try to do the 2 observations on 2 back-to-back days, if possible. The order that your baby receives routine care or care with the touch intervention is randomized. Randomized means that the order will be picked by chance, like tossing a coin or drawing straws. Each baby has a 50% (e.g. 50/50; 1 in 2) chance of receiving routine care on day 1 and a 50% chance of receiving care with the touch intervention on day 1. All babies in the study will receive both routine care and care with a touch intervention.

The touch intervention that your baby will receive during one of his/her "cares" includes 1 minute of touch before the start of his/her care, 30 seconds after his/her diaper change, and 1 minute at the end

of his/her care. To provide the touches, your baby's nurse will place one hand on the top of your baby's head and one hand across your baby's lower body. Your baby's nurse will not wear gloves during these touches to provide your baby with skin-to-skin touch. Your nurse will wash his/her hands (or use another approved method to disinfect his/her hands) before touching your baby.

The following activities will happen on each of the 2 days that we observe care. About 3 hours before the observed care, a researcher and your baby's nurse will place 3 extra heart monitor leads on your baby's chest and 2 extra monitoring patches, or leads, on your baby's foot. Leads are used in the NICU to monitor your baby and are sometimes changed to ensure good monitoring. The researcher and nurse will apply these extra leads during the first morning care before the observation starts so that your baby does not have to be disturbed again. If your baby's chest is very small, the nurse may move your baby's NICU monitoring leads to his/her back. For one hour before the observed care starts, we will collect information about how many times your baby is touched. We will collect information during the care about how your baby responds to the care and will stop collecting information 30 minutes after the care. It will be about 6 hours from the time your baby's nurse attaches the extra leads until the extra leads are removed. The figure below shows when information will be collected.

We will collect the following types of information about your baby's responses during care:

1) Hormone response: We will measure cortisol (a stress hormone) in your baby's saliva (salivary cortisol). We will collect a small amount of saliva (about 0.1mL or 1/50 of a teaspoon) using an absorbent medical sponge.. This will be similar to what nurses do when they provide oral care. It will take 2-3 minutes to collect the saliva. We will collect saliva 3 times – before your baby's nurse starts the care, 30 minutes after the nurse finishes your baby's care, and 60 minutes after the care ends.

2) Vital signs: Using a small external monitor and the extra leads applied earlier, we will measure your baby's heart rate before, during, and after nursing care. We will also look at your baby's heartbeat pattern to see how it changes before, during, and after the care.

3) Sweating: Using the 2 extra leads attached to your baby's foot, we will measure changes in sweating before, during, and after the care. These leads will be attached to equipment that measures sweating. Sweating is controlled by your baby's nervous system.

4) Behaviors: We will observe sleep behaviors during the 30-minute recovery period to determine if your baby is awake, asleep, or drowsy.

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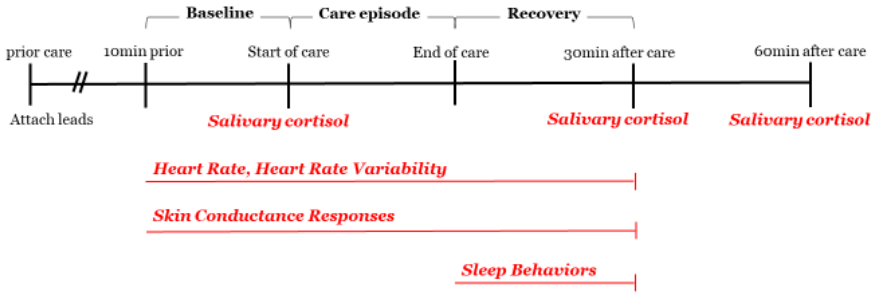

Figure 2. Timeline of study measures.

We will also collect background information from you such as your race and marital status on a form entitled "Mother Demographic Form" that you will complete. We will collect information from your baby's medical chart about your pregnancy and your baby's medical care. We will be collecting information about your baby's medical diagnoses, test results, and clinical procedures. We want to see if this background and clinical information affects how your baby responds to care.

When your baby reaches 35 weeks, we will perform a developmental test specially designed for preterm babies. During this test, we will see how your baby moves and how he/she responds to movement, the researcher's face, and soft sounds. If your baby is not medically stable or needs help breathing beyond a nasal cannula (small prongs that provide additional oxygen), we will wait to give your baby the developmental test until he/she is stable. If your baby's medical doctor is planning to send him/her home before he/she reaches 35 weeks, we will try to give your baby the developmental test before he/she leaves the NICU.

4) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen as a result of being in this study.

The leads may leave redness on your baby's skin when they are removed. This risk is similar to when your baby's nurse removes heart leads. We will ask nurses to use wet gauze to remove the leads to minimize this risk.

We expect that most babies will enjoy the extra touches that nurses will provide as part of this study, but a few babies may not. Your baby is normally touched during nursing care, so the comforting touches for this study do not increase the risk. We have stopping rules if your baby does not like the extra touches.

Even though the developmental test is made for preterm babies, some babies do not like the extra handling. The developmental test involves movement and handling similar to what he/she would experience on a normal day. If your baby does not tolerate the developmental test, we will end it.

Although we will take every precaution, there is a small chance of loss of confidentiality of your study information. We have locked filing cabinets and password-protected electronic databases to protect your baby's information for this study. We will also assign every baby a special study number and

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will use this number instead of his/her name to label study information. The key that lists both study numbers and names is encrypted and will be kept in a separate secure place.

There may be other risks of being in this research study that are not known at this time.

5) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

We expect that most babies will enjoy the comforting touches given as part of this study, but we cannot guarantee this. There are no other benefits to you or your baby from being in this study. We hope to learn something that could help other babies.

6) WHAT ARE THE COSTS AND REIMBURSEMENTS?

There are no costs to you to participate in this study. To thank you for allowing your baby to participate in this study, we will give your baby a small book when we observe the first care.

7) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study.

8) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice for your baby to be in this study. You may decide to stop your baby from being in this study at any time. If you decide to stop your baby from being in this study, call the study team at the number on page 1 of this form. If you stop your baby from being in the study, there will be no penalty or loss of benefits to which you are otherwise entitled.

If at any time the Principal Investigator believes that this study is not good for your baby, the study team will contact you about stopping. If unexpected medical problems come up, the Principal Investigator may decide to stop your baby's participation in the study.

9) OTHER IMPORTANT INFORMATION

If you are an employee of Nationwide Children's Hospital, the Research Institute at Nationwide Children's Hospital, The Ohio State University, or Ohio Health, your job or performance appraisal will not be affected in any way if you decline for your baby to participate or withdraw your consent for your baby to participate in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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 Web site at any time.

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If you are interested, the final study results will be shared with you once they are available. Please provide us with an email or address where we can send these results. However, at some time, a final study summary will be available on the ClinicalTrials.Gov (http://clinicaltrials.gov) website.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

10) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study includes information that can identify you or your baby. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to your health care provider to use or disclose (release) your health information that identifies you or your baby for the research study described in this form. Information collected is the property of Nationwide Children's Hospital, its affiliated entities, and/or the sponsor.

PHI that may be used or disclosed will include: Names, Birth Date, Admission Date, Discharge Date or Date of Death, Address and/or Email Address, Medical Record Numbers, Biometric Identifiers (Photographs, Video-recordings).

People or Companies authorized to use, disclose, and receive PHI collected or created by this research study:

- PI and study staff
- The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
- Nationwide Children's Hospital internal auditors
- The Ohio State University research team
- The Ohio State University Office of Responsible Research Practices
- The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research)

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may be further disclosed by them and no longer be protected by federal privacy rules.

Reason(s) why the use or disclosure is being made: to locate medical charts, to send study results or photographs (if requested)

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You may decide not to authorize the use and disclosure of your baby's PHI. However, if it is needed for this study, your baby will not be able to be in this study. If you agree to your baby being in this study and later decide to withdraw your baby's participation, you may withdraw your authorization to use your baby's PHI. This request must be made in writing to the Principal Investigator at 1585 Neil Avenue, Columbus, OH, 43210. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

PHI will only be shared with the groups listed above, but if your baby has a bad outcome or adverse event from being in this study, the study team or other health care providers may need to look at your baby's entire medical records.

The results from this study may be published but your identity and that of your baby will not be revealed.
A copy of this form and other research related health information may be added to your baby's NCH medical record.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or disclose your baby's PHI will not expire.

11) USE OF INFORMATION/SAMPLES FOR FUTURE RESEARCH USE

Information that identifies you or your baby may be removed from the study data and any samples that are collected during this research study. We may and your baby's data and/or samples for future research studies without your additional informed consent.

12) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions, concerns, or complaints about anything while on this study or you have been injured by the research, you have 24 hour access to talk to the Principal Investigator at 614-349-8788.

If you have questions, concerns, or complaints about the research; if you have questions about your rights as a research volunteer; if you cannot reach the Principal Investigator; or if you want to call someone else, call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

13) PERMISSION FOR PHOTOGRAPHS

With your permission, we may take photographs of your baby for future educational and scientific presentations. Your baby's personal identifying information will not be disclosed. We will only use your

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baby's picture in these presentations. If you would like a copy of your baby's digital photograph (if taken), please provide us with an email address.

I agree to allow my baby's photograph to be taken and used for educational and scientific presentations: (initial your choice)

_____ YES _____ NO

Email address for study results or photographs:

Email: _____

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Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

_____
Printed name of child

_____ _____
Signature of parent or individual legally authorized to consent to the child's general medical care — Date & Time AM/PM

_____
Printed name of parent or individual legally authorized to consent to the child's general medical care

_____
Relationship to Participant

If signature of second parent not obtained, indicate why: (select one)

- ❑ Not required by IRB
- ❑ Second parent is deceased
- ❑ Second parent is unknown
- ❑ Second parent is incompetent
- ❑ Second parent is not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

_____ _____
Signature of person obtaining consent — Date & Time AM/PM

_____
Printed name of person obtaining consent