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Title: Use Of Nfant® Technology Feeding System For Infants Less Than 30 Weeks GA

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USE OF NFANT® TECHNOLOGY FEEDING SYSTEM AS AN ADJUNCT TO VISUAL ASSESSMENT AND CUE-BASED FEEDINGS FOR INFANTS BORN LESS THAN 30 WEEKS GESTATIONAL AGE (GA)

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For Children (persons under 18 years of age) participating in this study, the term "You" addresses both the participant ("you") and the parent or legally authorized representative ("your child").

Purpose

We are asking you to take part in a research study. The purpose of this research study is to use a new medical device from NFANT Labs as we try to teach your baby how to suck and take milk from a bottle. The new **nfant®** device is FDA-cleared. The device has a sensor that can be put in special **nfant®** nipples or hospital nipples. The special nipples have a slower flow rate than our hospital nipples. As the baby tries to suck, the sensor will send information about the baby's suck to a program that will study the baby's sucking pattern. The program then shows us the pattern instantly on an electronic tablet as the baby sucks. The device will allow us to see what happens to the baby's suck when we change positions of the baby or the nipple. It will also let us see how the baby's suck pattern changes over time. This information may help us to make changes faster that may allow your baby to drink better from a bottle over time.

Description of Study Procedures

About 50 babies born early will take part in this study at Woman's Hospital.

Your taking part in this study will start when you sign the consent. Your taking part in this study will end after your baby goes home and you complete the phone follow-up questions.

When your baby gets to 31 to 32 weeks (weeks at birth plus every week of life after birth day), an Occupational Therapist/Physical Therapist (OT/PT) will see if your baby is off the breathing machine. If your baby is off the breathing machine, OT/PT will see if your baby can suck well on a pacifier. When your baby sucks well on a pacifier, OT/PT will get a first reading with the device, a NO FLOW nipple, and warm water. A Soothie pacifier will be used instead if the NO FLOW nipple is too big for your baby's mouth. If OT/PT cannot get a first reading, they will try again with the next visit. They will keep trying at each visit until the first reading is done. Once the first reading has been gotten, OT/PT will keep using the device with the NO FLOW nipple (or pacifier if mouth is too small) and warm water 2 to 3 times a week.

When your baby gets to 33 weeks and the first reading is done, OT/PT will get a reading to see if your baby is ready to start cue-based feeds. Cue-based feeding is a kind of feeding that is based on how ready your baby is for bottle feeding by looking at specific actions, or cues. This reading will be with the device, a NO FLOW nipple (or pacifier if mouth is too small), and warm water. If OT/PT cannot get this reading, they will try again with the next visit. They will keep trying at each visit until this reading is done. Once this reading has been gotten, OT/PT will ask your baby's doctor to write an order to start cue-based feeds. OT/PT will also keep using the device with the NO FLOW nipple (or pacifier if mouth is too small) and warm water 2 to 3 times a week until your baby is ready to take a bottle.

When your baby is ready to take a bottle, OT/PT will get a reading with the device, EXTRA SLOW FLOW nipple, and breast milk or formula. If OT/PT cannot get this reading, they will try again with the next visit. They will keep trying at each visit until this reading is done.

After your baby has finished with the start of bottle feeding reading, OT/PT will get a new reading with the device, a SLOW FLOW nipple, and breastmilk or formula at the next visit. If OT/PT cannot get this reading, they will try again with the next visit. They will keep trying at each visit until this reading is done.

After your baby has finished with the SLOW FLOW reading, OT/PT will get a new reading with the device, STANDARD nipple, and breast milk or formula. If OT/PT cannot get this reading, they will try again with the next visit. They will keep trying at each visit until this reading is done.

After your baby has finished with the STANDARD nipple reading, OT/PT will keep using the device 2 to 3 times a week. They will start with the STANDARD nipple and breast milk or formula. OT/PT may change to a hospital nipple instead if your baby does not do well with this STANDARD nipple. OT/PT will stop using the device when your baby has taken all bottles for 2 days.

You will get a phone call after your baby has gone home to ask if the baby was readmitted to a hospital from the time of discharge to 21 days after discharge. We usually call families after discharge to ask questions about your NICU experience and how the baby is doing. These questions will be added to that routine phone call to keep you from getting too many phone calls.

Risks

There may be risks we do not know about at this time. The risks for taking part in this study are small. NFANT Labs has given extensive training to the OT/PT's on how to use the device. Each device will be looked at and approved by our Information Systems Department for safety before it is used.

The sensor can possibly stop working. If the sensor stops working, it will not be able to send information to the program that shows the baby's suck pattern. It will not harm the baby in any way.

To not spread infection, each baby will have its own special nipples. The special nipples will not be shared with other babies. The special nipples will be cleaned with hot water and mild soap after use and thrown away after 24 hours. The sensor that goes in the special nipples will be cleaned with alcohol after use. The electronic tablet will be cleaned after use with a microfiber cloth.

Benefits

There may be possible benefits to your baby from taking part in the study. This may be:

- less time for your baby to be able to take all feeds by bottle,
- less time for your baby to need to stay in the NICU for feeding problems,
- smaller amount of exposure to radiation due to less need for swallow studies, and
- better sucking patterns.

Your baby may not directly benefit from taking part in this study, but things learned in this study may possibly help other babies in the future.

Alternatives to Taking Part

The alternative to taking part in this study is to not take part.

Can You Stop Being In The Study?

Taking part in the study is voluntary. You can stop at any time. Not being in the study will not involve and penalty or loss of benefits to which you are otherwise owed. Please call Nanette Gremillion at 225-231-5588, extension 3583 if you want to stop taking part in the study.

The investigator's or your baby's doctors can also take your baby off the study if to keep taking part would not be in your baby's best interest. They can also take your baby off if your baby gets an illness that would increase risks of taking a bottle or affect how food is broken down in the body. If your baby is taken off the study by the investigators or your baby's doctor, you will be told.

You will be notified of any new information which may affect your willingness to take part in the study.

Confidentiality

Your baby will be given a unique code number to be used instead of their name when using the device and sharing information with NFANT Labs.

We will keep your study records with identifiers at Woman's Hospital in a locked file cabinet or a password protected computer for 3 years after the study is done. The records will then be destroyed.

The electronic tablet will be kept in a locked cabinet in either your baby's room or the OT/PT office between uses for privacy. The sensor communicates wirelessly with a special mobile app. No protected health information is stored in or sent from the sensor. With the mobile app, 2 types of data are seen and saved: the feeding trace made by the device and patient information put in by OT/PT.

If the results of this study are published, you or your baby will not be identified in any way. Your personal information may be disclosed if required by law.

Although steps have been taken to maintain privacy, absolute confidentiality cannot be guaranteed.

Some entities may view or copy your study-related information. These entities include: Woman's Hospital Foundation Institutional Review Board, Woman's Health Research Department, Woman's Hospital Research and Development Committee, and federal agencies as required by law.

A description of this study 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 website at any time.

Collection Of Identifiable Private Information

Identifiers, with the exception of date of birth, will be removed from the data and could be used by Woman's Hospital, NFANT Labs, or another investigator to write new research studies in the future. Date of birth is needed for the device to figure out gestational age plus the days since birth of your baby each time it is used. Data with the identifiers taken off, except for date of

birth, will be stored in the NFANT Lab's database during the study and after the study is over. NFANT Lab's database uses large pieces of data to find trends in feeding babies born early that may be missed otherwise. This may help babies in the future.

Identifiers might be removed from data and the data that is not identifiable could be used for future research studies or distributed to another investigator for future research studies. This data may be given to investigators without additional informed consent from you or your representative.

Financial Information

You will not be paid for taking part in this study. NFANT Labs will provide the device, sensor, and special nipples at no charge to you. OT/PT services will be charged to you snd your insurance company based on time spent with your baby during visits. The visits are a routine part of a baby's care when they are born early. They will be done whether or not you take part in this study. It is not possible to know if using the device will add extra time to the visit. This is because how long OT/PT visits last change with every visit. How long the OT/PT visit will last is based on what each baby's health and energy allows.

Who Do You Contact For Questions About The Study?

If you have any questions about the study procedures, please contact the principal investigator, Nanette Gremillion, at 225-231-5588, extension 3585. For questions about your rights as a research subject, contact Ericka Seidemann, Human Protections Administrator, at 225-231-5296.

Woman's IRB
Approved 7/7/20
Expires

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to have your child participate in this study. You will receive a copy of this signed consent form.

_____
Name of Child (printed)

_____
Signature of Parent or Legally Authorized Representative Date

_____
Name of Parent or Legally Authorized Representative (printed) Relationship

_____
Signature of Person Obtaining Consent Date

Waiver of Assent

The assent of _____ (name of child/minor) was waived because of age.

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