Consent to Participate in a Research Study

Visual Stimuli & Maternal Scent and Their Influence on Suck Patterning in Infants
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We are inviting you and your infant to take part in a research study. This form will tell you about the study, but the researcher will also explain this in person and answer any questions you might have. When you feel you fully understand the study, you can tell the researcher whether or not you would like you and your infant to participate. If you do decide to participate, we will ask that you sign this form and you will also receive a copy for your records.

Why are my infant and I being asked to take part in this research study?
We are asking you to be in this study because you are a female parent/caregiver at least 18 years of age and your healthy infant is age six months or younger.

What is the purpose of this study?
An infant’s ability to engage in suck is an essential component of their oral-motor development, especially their ability to feed. Previous research has found that visual sensory stimulation may promote suck patterning in infants. To our knowledge, no previous study has examined whether maternal scent and visual stimuli can alter sucking, breathing rate, and heart-rate behavior in infants. Therefore, the purpose of this study is to examine whether social visual stimuli (female face), in the presence of maternal scent, can enhance infant suck and cardiorespiratory patterning (respiratory rate, heart rate, and heart rate variability). This information would be helpful in guiding parents and speech therapists through the process of selecting appropriate stimuli to help their infant to develop these necessary sucking/feeding skills.

What will my infant and I need to do and how long will it take?
We will request that you and your infant come to the Speech and Neurodevelopment Lab at Northeastern University, prior to your baby’s usual feeding time. Your infant will suck on a pacifier as two different pairs of visual stimuli, a female face and a car, are presented, in 4 separate 30-second time intervals on a computer screen. As part of this study, we are examining how maternal scent can influence infant’s looking, sucking, and cardiorespiratory behavior. To do this, we will send you a t-shirt to wear for three consecutive nights prior to the study. You will then bring this t-shirt with you on the day of the study in a sealed bag.

Once in the lab, your infant will be seated in a baby seat, in a semi-reclined position. We will ask that you observe the study through a one-way mirror in the room next door. The researcher will be present in the room with your infant. The t-shirt that you wore will be placed on your infant’s upper chest, right below the chin as he/she is presented with the visual stimuli. As your infant sucks, we will collect data on his/her suck patterning. Your infant’s eye gaze toward the stimuli displayed on the computer will be recorded by a video camera.

We will also attach three electrodes to your infant’s chest (two on the upper chest and one on the lower abdomen) to measure heart rate. These sensors are adhered to your infant’s skin through a
safe, gel adhesive that is commonly used with neonates. In addition, a respiratory belt will be placed around your infant’s abdomen to measure breathing rate. This belt can be placed directly on the skin or over a thin onesie. Your infant’s eye-gaze will also non-invasively be tracked throughout the study.

The entire visit to the lab should take approximately 1 hour.

**Are there any potential risks or discomforts to my infant?**
We do not anticipate any risks or discomforts associated with this research study. If your baby shows signs of any discomfort throughout the study, testing will be discontinued. To ensure safety precautions, all pacifiers will only be used once per infant then will be discarded.

**Will my infant benefit from this research study?**
There are no direct or immediate benefits from your infant participating in this study. However, the information gathered from this study could benefit other infants in the future.

**Will it cost me anything to participate?**
No cost is associated with participating in this study.

**Will I receive compensation for my infant’s participation?**
You will receive a baby-friendly gift for your participation in this study. Options include baby rattles, musical toys, balls, and blocks. In addition, we will pay for the cost of your parking at Northeastern University during your study session.

**Who will see the information about my infant?**
The Principal Investigator and Research Assistant will be the only people with access to study information. All study data will be stored in locked files in the Speech and Neurodevelopment Lab. With your permission your infant will be recorded using audio and visual recording devices during the study for the purpose of including the audio and visual files together with our other measures for review and analysis in the lab by the research team. This information will be kept confidential. If you do not feel comfortable having your infant recorded, please inform the experimenter and the audio-visual equipment will be turned off during the study. Requesting that your infant not be recorded does not exclude you from participating in this study. Any reports or publications based on this research will use only group data and will not identify you or your infant as being of this project.

**Can I stop my infant’s participation in this study?**
You and your infant’s participation in this study are completely voluntary. You may choose to stop participating at any point during the study. There will be no repercussions should you decide you no longer wish to participate.

**Who can I contact if I have questions about my infant’s rights as a participant?**
If you have any questions about your and your infant’s rights as participants in this research study you may contact you may contact Nan C. Regina, Director, Human Subject Research Protection, 490 Renaissance Park, Northeastern University, Boston, MA 02115. Tel: 617.373.4588, Email: n.regina@neu.edu. You may call anonymously if you wish.
Who can I contact if I have questions about the study?
If you have any questions, concerns, or problems you may contact the Research Assistant, Courtney DeSousa, by email at desousa.c@husky.neu.edu or the Principal Investigator, Dr. Emily Zimmerman at e.zimmerman@neu.edu or (617) 373-4670.

Is there anything else I need to know?
Exclusion criteria include infants that were preterm birth, have serious medical diagnoses, vision difficulties, skin sensitivities/allergies to adhesives and/or diagnosed feeding problems.

By signing below, I confirm that I understand the information presented on this form and agree to let my infant participate in this research study. My preferences regarding recording of the session are as follows:

____ I agree to have the study session recorded for review and analysis by the research team.

____ I do not want the session recorded.

________________________________________________________________________
Signature of Parent/Guardian                           Date
________________________________________________________________________
Printed name of Parent/Guardian
________________________________________________________________________
Printed name of Infant
________________________________________________________________________
Signature of person who explained the study
________________________________________________________________________
Printed name of person who explained the study
Northeastern University, Department of Communication Sciences and Disorders
Name of Investigators: Emily Zimmerman, Ph. D and Courtney Lynn DeSousa, Research Assistant
Title of Project: Visual Stimuli & Maternal Scent and Their Influence on Suck Patterning in Infants

Future Use of Audio and Video Recordings

In addition to having recordings analyzed in the lab by the research team, we would also appreciate your consent to use the audio and video recordings of your infant’s study session to demonstrate sucking behavior and patterns. Audio, video and still images would only be used in educational contexts and may be reproduced in various mediums (e.g. slide presentations, print publications, video, internet/world wide web, and/or other media formats and platforms). The images may include your infant’s entire face or just the mouth while sucking on the pacifier. Viewers of the recordings may be able to recognize your infant, but neither your name nor your infant’s name will ever be associated with the recording.

This consent is entirely separate from your consent to participate in the study and may be withdrawn at any time in the future. To give your permission to have the recordings potentially used in educational contexts, please sign below. Please note that if you do not wish to give your permission for this, you may still participate in the study.

I have read and understand the above and agree to potentially have an excerpt from my infant’s recorded study session shown for educational purposes.

Name__________________________________________________________

Signature__________________________________________ Date__________

APPROVED