Official Title: Assessing Better Bottles for Babies (AB3)

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Duke University Health System

Consent to Participate in a Research Study
ADULT
AB3: Assessing Better Bottles for Babies

KEY INFORMATION SUMMARY

The purpose of this research study is to learn about how different bottles may affect a baby's growth and your feeding of your baby. The study includes filling out some forms with questions about your baby and your thoughts about your baby's growth and health. We will also ask you to video-record yourself for 2 feeding sessions. You will also be assigned to get bottles of a certain size and certain design (clear or not-clear) to use over the first 4 months of your baby's life. We will also collect information on your baby's growth from their medical records. Some parents may receive phone calls and/or text messages between their baby's regular visits with their doctor as well. The study takes place from soon after birth through your baby's first four months of life. The estimated total time of interaction between the study staff and parents during the study period is 2 to 4 hours.

The greatest risks to this study would be feeling uncomfortable about answering some of the questions and your baby taking time to get used to new bottles.

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

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you by the study team.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Charles Wood will conduct the study. The study is funded by a grant from the National Institutes of Health. Portions of Dr. Wood and their research team's salaries will be paid by this grant.

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Why is this study being done?
The purpose of this study is to understand how infants grow and feed while using different infant bottle designs.

Up to 80 people will take part in this study at Duke.

What is involved in the study?
If you agree for yourself and your baby to be in this study, you will be asked to sign and date this consent form. You will be asked to fill out some questionnaires about your baby's eating and feeding behaviors.

Like drawing numbers from a hat, your baby will have a one in four chance of being in one of four groups for the first 4 months of your baby's life. After you are randomized into one of the four groups, you will receive a set of baby bottles that you should use to feed your baby for the following 4 months, until you are told to no longer use them. The bottles will vary in size and style. Some parents will be given clear bottles and some parents will be given stainless steel metal. We will ask you to use these new bottles for the entire 4-month study. If you need more bottles, we will be happy to provide those. We ask that you do not use any bottles other than the ones given to you as part of the study during the 4-month study.

If you agree to participate, you will also be asked to video-record two feeding sessions with your baby in your home, or in-person at clinic if you prefer. The first session will be soon after you agree to participate, and the second session will be at the time of the study end, when you baby is 4 months old. We will ask you to set up a smart phone, tablet, or laptop to join a Zoom with a member of our study team. Our study coordinator will help you by giving you verbal instructions to set up the recording device and feeding video. In addition to recording the feeding session, we will ask you to weigh your baby's bottle that they are being fed before and after the feed and give this information to our study coordinator. After you feed your infant, the study coordinator will ask some questions about the feeding.

You will be in contact with our study coordinator at each of your baby's visits at their clinic and by phone or text in between each visit. During these times of contact, you will be asked a series of questions related to your baby's feeding and the use of the bottles you were given.

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We will also collect some information from your and your baby's medical charts, including birth information, vital signs from pregnancy, and weight and length, labs and diagnosis information from birth until up to 6 months after they have completed their two year-old routine clinic visit.

Will I be given research results that may affect my medical care?
We do not expect to learn anything through this research that will affect your medical care. Clinically relevant results of this research will be communicated with you at the end of our process of analyzing the data. You will be given information about feeding and growth on average of the overall group that you were assigned to.

How long will I be in this study?
This study will last for approximately four months after your baby was born, or until after your baby has had their routine 4 month-old visit with their provider in clinic. We will continue to collect information about your baby's growth until 6 months after they have completed their two year-old routine clinic visit. You can stop participating at any time without penalty. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

What are the risks of the study?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose. Your baby may experience some fussiness or gassiness related to differences in the bottle designs. Your infant may dislike using the bottles we offer during the study. It possible that your formula could sour or spoil if not handled correctly. Additionally, it is possible that your infant may be allergic to the materials used to make the bottles and nipples we will use in the study.

There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

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Are there benefits to taking part in the study?
If you agree to take part in this study, there may be direct medical benefit to your baby including improved feeding and growth. We hope that in the future the information learned from this study will benefit all families who decide to feed their baby with a bottle.

Will my information be kept confidential?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share the feeding videos with our collaborators at California Polytechnic State University (Dr. Alison Ventura and her team), who will be reviewing them as part of the study. Only authorized members of her team will be able to access the videos, in a secure manner. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

All study personnel are mandated reporters of suspected child abuse and neglect. Thus, all study personnel are prepared to identify and report any signs of child abuse or neglect. During home or video visits, study staff who have reasonable suspicion or observe any signs of physical, sexual, or emotional abuse, or neglect of infants or any children under the age of 18 will immediately notify Dr. Wood and a telephone report will be made to child welfare services and the local Police/Sheriff's department. Information about the study participant may be disclosed in this report.

As part of the study, results of any study-related tests or procedures may be shared with the National Institutes of Health and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include:

- representatives and affiliates of the National Institutes of Health,
- the Duke University Health System Institutional Review Board

If any of these groups review your research record, they may also need to review your entire medical record.

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Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record. Your child's medical record may be accessed up to 6 months after they have completed their two year-old routine clinic visit.

If you choose to be in this study, data collected from you that can be used for future research will be stored long-term in a repository, the Duke Research Data Repository, following the completion of the study. Any personal information that could identify you will be removed or changed before files are stored in this repository for use by other researchers or results are made public. The removal of this information allows your data to be used without anyone knowing which person in the study it comes from.

The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely. Data will be available in the Duke Research Data Repository for a minimum 25 years after deposition.

This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain confidential. If you decide to share your information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

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The National Institutes of Health (NIH) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

There are some important things that you need to know about the CoC:

> It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
>
> It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.
>
> It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

Will it cost me anything to be in the study?
There are no additional costs to you for participating in this study. You and your insurance company will not be billed for your participation.

We will provide you with a set of baby feeding bottles to you as part of your participation in this study. At the end of the study, or if you decide to stop being in the study before it ends, you will not be asked to return the bottles.

Will I be paid to be in the study?
You will receive up to $80 for your expenses related to your participation (parking, gas, and time). $20 will be given at enrollment and completion of the initial

questionnaire. $20 will be given at the completion of each of 2 video recordings. And the final $20 will be given at completion of the final questionnaire. You will only be paid for the visits you complete. In order to issue your payment, Duke University may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

What about research related injuries?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Charles Wood at 919-620-4772 during regular business hours and at 919-970-7037 after hours and on weekends and holidays.

What if I want to withdraw from the study?

If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Charles Wood in writing and let them know that you are withdrawing from the study. Their address is Charles.wood@duke.edu.

Your doctor may decide to take you off this study if your baby's growth changes more than expected or if your study doctor determines that it is no longer in your best interest to continue. Reasons why this might occur include differences in growth of weight and length that are more than expected. The sponsor or regulatory agencies may stop this study at any time. If this occurs, you will be notified and your study doctor will discuss other options with you.

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We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your baby's weight, length, and feeding volume, type, and frequency may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Whom should I call if I have questions or problems?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Wood at 919-620-4772 during regular business hours and at 919-970-7037 after hours and on weekends and holidays.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree for myself and my baby to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Participant	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time