

Frequently Asked Questions (FAQS)

1. What is the purpose of this study?

The purpose of this study is to determine: 1) how the gut bacteria of exclusively breastfed infants changes in response to ingesting solid foods; 2) how infant cognition develops in response to ingesting solid foods; and 3) the relationship between infant gut bacteria and infant cognition during the first year of life.

2. What complementary foods are you using in this study and why?

We are trying to understand how specific complex carbohydrates in commonly used first foods encourage the growth of different bacteria in the infant gut. The two foods we are using in this study are commercially-available pears and sweet potato. We have chosen these specific foods because they differ substantially from each other in their carbohydrate make-up. For example, sweet potato is made up of digestible carbohydrate called starch and pear is made up of other types of sugars found in fruits and vegetables. Thus, the difference in their carbohydrate make-up will provide a good contrast for comparing how bacteria respond to each type of carbohydrate. One food used in this study will be *Just Sweet Potato* by Plum Organics and the other food is *Earth's Best First Pears*. The foods chosen in this study are considered hypoallergenic and should not elicit an allergic reaction in your baby.

3. How do I feed the study foods to my baby?

When your exclusively breastfed baby is developmentally ready for solid foods, she/he will enter the Feeding Intervention Phase and will be randomized to one of two feeding groups: 1) pears first, then sweet potato; or 2) sweet potato first, then pears. During the Feeding Intervention Phase you will also be asked to continue to breastfeed (or breast milk feed) your baby. You will be instructed to feed the first study food (and breast milk) for seven days, followed by exclusive breastfeeding or breast milk feeding for four days; then the second study food (and breast milk) for seven days, followed by exclusive breastfeeding or breast milk feeding for four days. You will be instructed to offer 1-2 tablespoons of pears or sweet potato to your baby at least three times per day for seven days in a row (Study Days 8-14 and Days 19-25). On the first day of feeding each food (Days 8 and 19), you will be instructed to offer the food to your baby on two occasions: once in the morning and once in the early afternoon to provide yourself enough time to monitor and address any potential adverse reactions (such as rash, vomiting, etc.).

4. Why am I asked to open a new food pouch at each meal-time rather than reuse the previously opened pouch?

We ask that you open a new pouch of food at each meal-time in order to provide your baby with the freshest food that is also room temperature. Room temperature food tends to be more widely accepted by babies than cold food.

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5. How much of the study food does my baby need to eat each day?

There is no minimum or maximum amount of the study food that your baby is required to eat each day. It is only required that you offer the study food during at least three mealtime sessions a day. You'll find that you may have to offer the food 15 to 20 times before your baby will begin to like it or even try it. It is expected that your baby will eat between 1 and 2 tablespoons at each feeding but this amount will vary depending on your baby.

6. When am I able to introduce non-study foods to my baby?

You may begin introducing any other solid foods to your baby on or after study Day 30.

7. Why am I being asked to stop feeding my baby solid foods and exclusively breastfeed for four days after each week of feeding the study foods?

We ask you to follow each week of feeding the study foods to your baby with four days of exclusive breastfeeding in order to return your baby's gut bacteria back to that of an exclusively breastfed baby who has not yet consumed solid foods. The gut bacteria respond relatively quickly to changes in diet at this age and four days is long enough to "wash-out" the changes to your baby's gut bacteria by the solid foods. This way we can gain a better understanding of how each study food individually impacts gut bacteria.

8. What should I do if I miss a day of feeding my baby the study food?

If you miss feeding your baby the study food on one or more days, please **do not** feed the missed food after the one week feeding period has ended. Just keep track of how often and how much food your baby consumed in your Study Food Log during the feeding period.

9. Will I be dropped from the study if I do not exclusively breastfeed my baby?

Throughout the first month of the study, babies are required to be exclusively breastfed without the use of infant formula or non-study solid food. However, if you feed your baby some amount of infant formula or solid food once you are enrolled in the study, you will not be dropped from the study.

10. What samples do I need to collect for the study?

You will be asked to collect 7 breastmilk and 3 stool samples from yourself, and 18 stool samples from your baby's diaper and 1 saliva sample from your baby over the 6-month study period.

11. How will I collect the samples?

You will receive detailed instructions for collecting all samples by study personnel after you are enrolled into the study. You will be provided with collection supplies and instructional handouts to use at home. Please contact the study coordinator for help if you are experiencing trouble collecting samples.

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12. Why do I need to dedicate the same breast for all milk collections?

Because we are comparing fats, sugars and proteins in milk among all the women in the study and because there are differences between the left and the right breast, we ask that you select either your left OR your right breast to collect from throughout the entire study period. This is our method for standardizing milk collection to ensure the differences we observe are real.

13. Why do I need to collect a milk sample at least 2 hours after feeding my baby?

Because we are comparing fats, sugars and proteins in milk among all the women in the study and because the fats, sugars and proteins in milk are different throughout the day and influenced by when you last fed your baby, we ask that each mom collect a milk sample from a “full” breast. Your breasts are likely to be full at least 2 hours after you have last fed your baby. This method ensures milk collection is the same among all mothers in our study so that the differences we observe are real.

14. Why do I need to hand-express or pump 4 teaspoons (20 mL) of milk but only collect 2 teaspoons (10 mL) of it into collection tubes for the study?

Because we are comparing fats, sugars and proteins in milk among all the women participating in the study and because fats, sugars and proteins in milk are different for the first milk (foremilk) and last milk (hindmilk) that is expressed from the breast, we ask moms to take a small sample (10 mL) from the first 20 mL of their full breast. You can feed the remaining 10 mL to your baby. This is our method for standardizing milk collection to ensure the differences we observe are real.

15. Why am I instructed NOT to place baby wipes in the diaper as I collect stool?

It is very convenient to place wipes into the diaper while changing your baby but please do not do so until after you have finished collecting your baby’s stool for the study. The detergents in the wipes could kill some of the bacteria we are studying. You can place the wipes into the diaper after transferring the stool into the collection tube.

16. Why am I instructed NOT to use diaper creams the night before or the day of an infant stool collection?

Many active ingredients used in diaper creams or other anti-rash treatments interfere with our method for measuring bacteria. For this reason, we ask that you not apply diaper creams or other diaper treatments to your baby’s rear-end and genital area the night before or on the day a stool sample is requested until after the stool sample has been collected. Once you have collected the stool sample, you may use diaper creams. If you are concerned about diaper rash, you can reduce it by changing your baby as soon as he/she passes a bowel movement, and also by gently washing away the stool from your baby’s rear-end and genital area in a lukewarm water bath instead of using wipes, which can irritate the skin. Finally, if

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your baby is uncomfortable and requires diaper cream or anti-rash treatments for relief, then please apply either and let us know on your collection kit label. Your baby's comfort is extremely important to us and we would not want to reduce his/her comfort in any way.

17. How do I store the samples and for how long?

You will be asked to store all collected samples in your home freezer. We will provide you with sealable Ziploc bags and a plastic freezer box in which to store your samples in your home freezer to prevent food from being contaminated. You will be asked to store the samples for 1-4 weeks until study personnel will collect them during your next scheduled home visit.

18. Why is it important that stool samples are immediately stored in the freezer upon collection?

Freezing will preserve the bacteria found in your baby's stool. Since we are interested in measuring the bacteria that is in your baby's gut and not those that grew because the sample was not frozen right away, it is important that you store your baby's stool samples in the freezer immediately after collection. To reduce frozen stool samples from thawing, please store your plastic freezer box that contains the samples inside the larger area of your freezer and not in the freezer door that is frequently opened and closed.

19. Why am I asked to fill out 4 different daily logs during the Lead-in and Feeding Intervention Phase?

The four logs will ask you to check boxes "yes" or "no" to tell us about what your baby consumes each day, such as infant formula or other beverages, medications, and antibiotics, as well as report the health of your baby. They will also ask you to rate your baby's gut symptoms and general health before and during the introduction of solid foods. During the two weeks of the feeding intervention we will ask you to record the weight of the food your baby consumed each day on the logs. These logs haven been designed to be short and should only take a few minutes to complete.

20. Which Infant Vocalization Recorder are you using in the sub-study and is it safe?

Participants who agree to be enrolled in the Infant MiND Infant Vocalization and Activity Monitoring Sub-study will receive a LENA™ digital language processor (www.lena.org). The LENA™ is a commercially available, non-invasive digital language processor that will record your baby's auditory environment (i.e. the language spoken to him or her, and all the vocalizations he or she makes). LENA recorders are completely safe and meet U.S. and international standards for electronics and toys. The device is a small, 2 ounce, wireless audio recorder that slides into a foam-backed pocket on the front of custom clothing. They have no small parts that might come loose or create a choking hazard. Unlike cellphones, LENA recorders don't transmit any signals; they use the same type of low-power processor used in hearing aids. Both the recorder and the clothing are products of the LENA Research Foundation (www.lena.org).

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21. Which Infant Activity Monitor are you using in the sub-study and is it safe?

Participants who agree to be enrolled in the Infant MiND Infant Vocalization and Activity Monitoring Sub-study will receive a MonBaby™ baby monitor (www.monbaby.com). The MonBaby™ is a commercially-available wireless baby monitor that is about the size of a half-dollar and snaps onto any article of a child's clothing, just like a button. It uses low power Bluetooth technology to connect to your smart phone so that you can monitor baby's breathing movements, body position, and fall detection. The Federal Communications Commission (FCC) Declaration of Conformity, sometimes called an FCC label, is a mark used on electronic products made or sold in the U.S. It demonstrated that MonBaby's Bluetooth radiation levels fall well within what's deemed acceptable by the FCC organization.

22. Will I be compensated for being in the study?

Yes. Participants can receive a total of up to \$410 in Target gift cards over the 6 month study period.

23. Who can I talk to about the study to answer my questions?

You can call the principal investigator Dr. Jennifer Smilowitz at 310-403-4483, or the Study Coordinator Chelsea Cook at 916-524-9034. More information about the research is available on our website: www.infantmind.ucdavis.edu