

Protocol Title: Strong Families Start at Home/ Familias Fuertes Comienzan en Casa: A Home-based Video and Motivational Interviewing Intervention to Improve Preschoolers Diet Quality and Parental Food Parenting Practices

NCT: Not Yet Assigned

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Version Number: 1
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BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

Strong Families Start at Home

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KEY INFORMATION:

You and your child have been invited to take part in a research project. It is described below. Your participation is voluntary. The researcher will explain the project to you in detail. Feel free to ask questions. If you have more questions later, Dr. Alison Tovar (401) 863-7327, the person mainly responsible for this research project will discuss them with you. If you decide to participate, you will be asked to sign this form for yourself and on behalf of your child. This form will be a record of your agreement to participate. It will also be a record of your child's participation. You will be given a copy of this form to keep.

Important information to know about this research study:

- **PURPOSE:** The purpose of the study is to compare two six-month, home-based programs and look at how it affects children's health.
- **PROCEDURES:** If you choose to participate, each parent and their child will be "randomized" into one of two groups. This means that you are put into a group by chance, like a lottery or by flipping a coin. One group will focus on child feeding and the other group will focus on your child's reading readiness. In either group, you will participate in-home and telephone sessions with a support coach, and you will receive materials and text messages about healthy meals or reading readiness.
- **TIME INVOLVED:** Your participation in the study will last 6 months. In total, it will take you about 8-11 hours of your time to complete the study.
- **COMPENSATION:** You will receive \$250 for your time and participation; \$50 will be paid at the beginning, \$100 at the 6-month follow-up, and \$100 after you complete the follow-up session at 12-months. If you send a video recording of a family meal or reading time with your child for home visit 3, your name will be added to a raffle to win an additional \$150 gift card.
- **RISKS:** Risks or discomforts from this research study are minimal. You might feel uncomfortable providing some information.



- **BENEFITS:** The information that you provide may help us understand how to help families promote healthy eating or reading. We can use this information to develop future programs for families.
- **ALTERNATIVES TO PARTICIPATION:** Taking part in this research project is voluntary. You and your child don't have to participate, and you can stop it at any time.

1. Researcher(s):

Principal Investigator: Alison Tovar

Office: (401) 863-7327 Email: alison_tovar@brown.edu

Project Coordinator: Andrea Ramirez

(401) XXX-XXXX Email: andrea_ramirez@brown.edu

2. What is this study about?

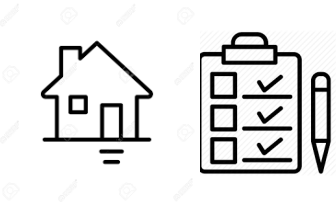
The purpose of the study is to test a program to help improve children's wellness and development for children ages 2-5 years. It is important to develop programs that may help families raise healthy children. This study will tell us how well these programs work.

You are being asked to participate because you are at least 18-years old and have a child between 2 and 5-years old, and identify as Latino/Hispanic.

3. What will I be asked to do?

During the 6 months, you will be working with a support coach, who will visit you at your home once a month, for three months, and call you over the phone, once a month for three months. You will also receive written materials and text messages during this time. Participating in this project will take 8 - 11 hours of your time.

The project includes the following:

<p>First Home Visit: Measurement</p> 	<ul style="list-style-type: none">• You and your child will participate in a 60-75 minute home visit. We will come to your home. We will collect information from you in a survey. In this study we will ask you about your family characteristics, what your child ate over the past day, the feeding practices you use with your child, and your food home environment. Some of these questions may make you uncomfortable or bring up unpleasant feelings or memories. You can refuse to answer or skip any questions you do not want to answer.• We also measure your and your child's height and weight. We will also measure your and your child's dermal carotenoids (a substance in your skin that gives
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information about fruit and vegetable intake) by using a device called Veggie Meter, by placing your finger on the lens for 10 seconds.

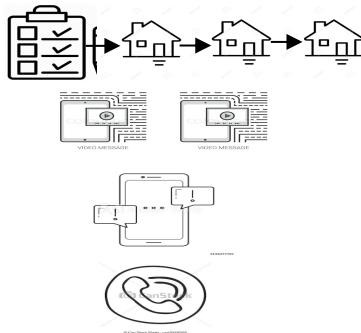
- We will check the availability of some foods and food preparation equipment in your home. To do so, we will ask you to show us the food item or equipment to confirm that you have them in your home, either in the refrigerator, pantry, other food storage areas, or any other section of the home. To minimize the feeling of invading your personal space, we will ask you to walk us through the kitchen areas you feel comfortable with. If you do not feel comfortable doing this or if any other household members would be disturbed by us being in the kitchen, you can decide to skip these questions.

- Within a week after the visit, we will call you to ask what your child ate over the past day. This phone call will last approximately 20-30 minutes.



At the end of this visit, we will select an envelope to see what group you will be participating in: Group 1: Feeding your child, OR in Group 2: Reading Readiness. Unfortunately, you cannot choose the group.

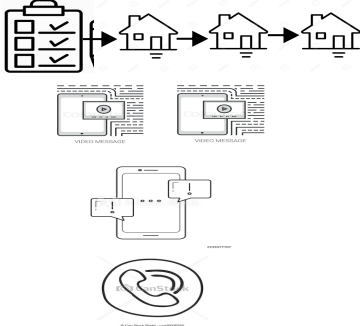

Group 1: Feeding your Child Group



If you end up in this group, you will get:

- In addition to the measurement visit, there will be three more home visits by a support coach, once a month for three months. Visits will last about 60-70 minutes. We will discuss how to help you make cooking and eating healthy easier!
- For one of the visits, a culinary intern will join the session along with the support coach and you, to prepare a recipe (ingredients will be provided), teach you about basic cooking skills, and how to involve your child in food preparation. You will choose a recipe from our cookbook, and we will consider any allergies you, your child or any family members might have.



	<ul style="list-style-type: none"> ➤ For one of the visits, we will ask you to record one typical family meal on your cell phone. Then you will upload the video to a secure app. The research assistant will show you how. ➤ Text-messages will be sent two times/week. The messages will include special content just for you and your child. Links to recipes and video clips of easy food preparation will be included. Receiving too many text messages can result in additional costs for you depending on your phone plan. ➤ During the last three months of the study, you will receive written materials and phone calls once a month.
<p>Group 2: Reading Readiness Group</p> 	<p>If you end up in this group, you will receive:</p> <ul style="list-style-type: none"> ➤ In addition to the measurement visit, there will be three more home visits by a support coach, once a month for three months. Visits will last about 60-70 minutes. We will discuss how to help your child get ready to read. ➤ For one of the visits, we will ask you to record you and your child reading or looking at a book together on your cell phone. Then you will upload the video to a secure app. The research assistant will show you how. ➤ Text-messages will be sent two times/week. The messages will include special content just for you and your child. ➤ During the last three months of the study, you will receive written materials and phone calls once a month.
<p>Home Visit: 6-month follow-up</p> 	<ul style="list-style-type: none"> • Like the first home visit, you and your child will participate in another 60-75 minute home visit. We will collect the same information from you as the first visit. We will also measure you and your child's height, weight, dermal carotenoids, and check the availability of some foods and food preparation equipment. • We call you within one-week of the visit to ask what your child ate. This call will last about 20-30 minutes.



Final Home Visit: 12-month follow-up



- Like the first home visit, you and your child will participate in another 60-75 minute home visit. We will collect the same information from you as the first visit. We will also measure you and your child's height, weight, and dermal carotenoids, and check the availability of some foods and food preparation equipment.
- We call you within one-week of the visit to ask what your child ate. This call will last about 20-30 minutes.

4. Will I be paid?

You will be paid \$50.00 after the first measurement visit (\$35 after the home visit and \$15 after the phone call to find out what your child ate) and \$100 during the 6-month follow-up (\$75 after the home visit and \$25 after the phone call to find out what your child ate), and \$100 during the final measurement visit (\$75 after the home visit and \$25 after the phone call to find out what your child ate). This will add up to a total of \$250, if you complete all the sessions and follow-up visits. If you leave the study early you will only be paid for the visits you completed. This compensation will be provided in gift cards.

If you send a video recording of a family meal or reading time with your child for home visit 3, your name will be added to a raffle to win an additional \$150 gift card. Your odds of winning will depend on the number of participants who also send the video.

Both study groups will receive small gifts during the second home visit. The gifts you get will depend on whether you are in Study Group 1 or 2. These gifts could include cooking supplies or books.

There is no cost to you to be in this research study.

5. What are the risks?

Risks or discomforts from this research study are minimal. There are some potential emotional risks, for example, you or your child may feel uncomfortable or embarrassed when answering questions about yourself or your family, taking and sharing videos of your family eating or reading, or by having research staff come to your house. You or your child may also feel uncomfortable or have anxiety when weight measurements. The likelihood of these risks happening is low, and the seriousness of these risks is low. We will try to make you feel as comfortable as possible, we are just learning about your experience with your child so that we can help other families. There are no right or wrong answers to the questions. You can choose not to answer specific questions or take a brief break from data collection. Also, audio



recording of the sessions can be stopped at any moment. The video recordings will help us know you better so that we can give you recommendations that better adjust to your family.

Even though we will try to keep your information confidential, there is always the possibility of a breach of confidentiality, and loss of privacy. The likelihood of these risks happening is low, and the seriousness of these risks is low. To minimize this risk and ensure privacy and confidentiality, laptops and iPads used to collect data will be encrypted and password protected. Signed Informed Consent Forms and paper screening forms will be kept in a locked file cabinet. In question 7, we will detail more how we are going to protect your information.

For one of our home visits, you will be preparing a recipe with your child. Food allergies are very common in the United States, therefore, we will make sure that the ingredients we provide will not produce any allergic reactions to any of your family members. During our baseline visit, we will ask you about any food allergies that you, your child or any other household members have. You will choose a recipe from our cookbook that you will feel comfortable preparing with your child. Since allergies can develop at any point through life, we will also share a handout with food allergy information, and what to do if anyone in your family experiences a food allergy.

6. What are the benefits?

You may not directly benefit from being in this research study. However, you and your family may learn some skills that could help you establish healthy routines with your child around eating or reading/verbal interactions.

What are the possible benefits to other people?

It is very important that we learn what programs work for parents of preschool children. This research study will help us do that. This study could help us develop future programs for families with young children.

7. How will my information be protected?

You and your child's data will be collected on iPads using a secure program that only certain study personnel can access. These iPads and the laptops used to collect and keep your information will be password protected and encrypted. This document (consent) will be kept in a locked file cabinet. We will also be audio recording the home visit and the phone calls, for quality control purposes. We will keep these audio recordings, as well as the video recordings in a safe server.

During your participation in the study, we will keep some information that might identify you (your name and contact information), but once data collection is complete, we will delete any information that identifies you.



The data will then be saved and sent to a researcher at Brown University. This data will not include any information that could identify you. To protect your identity, your data will only be identified with an ID number. All the information you provide will be confidential. The video and audio recordings, and the consent will be kept for five years and then destroyed.

We will share information with investigators outside Brown University, but this data will be unidentifiable, and shared through a secure server.

The information from this study may be published in scientific journals or presented at scientific meetings. All such data will be summarized for the entire group. It will not include any information that could identify you or your child.

We will do our best to make sure that the personal information gathered for this study is kept private. The only people who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person, agency, or sponsor as required by law. However, we cannot guarantee total privacy, and if required by the law, your personal information may be disclosed. If research staff have any concerns that they have witnessed child abuse or neglect, we will be required to issue a report. This report will be required when: a) research staff has reasonable cause to know or suspect that a child has been abused or neglected; b) any act or failure from the parent that can result in death, serious physical or emotional harm, sexual abuse or exploitation; or c) any acts or failure to act that results in an imminent risk or serious harm.

In addition, Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality. Authorized representatives from the National Institutes of Health may also review your research data to monitor or manage the conduct of this study.

8. Are there any alternatives to this study?

Your participation in this study will not interfere in any way with you and your child's standard of care. Deciding to participate or not to participate will have no impact on the services you receive from the WIC clinics or any other services. You should continue with your regular standard of care during and after your participation in this study.

9. What if I want to stop?

Your participation in this study is voluntary. You and your child can decide to stop participating in this research study. You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time. You may decide not to participate or stop participating, without penalty or loss of benefit to which



you are otherwise entitled or already have. To withdraw from the study, just tell a research team member by phone, email, or in person.

If you refuse to participate in or leave the study, your current or future relationship with Brown University, WIC clinics or any other organizations, will not be affected.

10. Who can I talk to if I have questions about this study?

Your welfare and that of your child is the concern of all research team members. If you have any questions about your participation in this study, or any problem as a direct result of being in this study, you should contact one of the people listed at the beginning of this consent form.

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

12. Consent to Participate

You are voluntarily making a decision for you and your child, whether or not to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered (4) you have decided to be in the research study and (5) you have decided on behalf of your child that they will be in the research study. You will be given a copy of this consent form to keep.

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

Parent participation

Participant's Signature and Date

/

Name of participant (Please print)

Child Participation



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Version Number: 1
Date: 09/07/2022

Signature of parent (on behalf of child) and Date / Name of participant (Please print)

Investigator certification:

My signature certifies that all elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the participant possesses the capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Research Staff Signature and Date / Name of staff (Please print)