

Alison Tovar
Nutrition and Food Sciences
Strong Families Start at Home
April 2, 2019

You and your child have been invited to take part in a research project. It is described below. 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) 874-9855, 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.

Strong Families Start at Home



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Project Coordinator: Katelyn Fox Office (401) 542-9105 Email: katelyn_fox@uri.edu

Important information to know about this research study:

- The purpose of the study is to compare two six-month, home-based programs and look at how it affects children's health.
- 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 healthy meals for your child and the other group will focus on your child's reading readiness.
- It will take about 6-13 hours of your time to complete the study.
- Risks or discomforts from this research study are minimal.
- 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.
- You will be paid \$150 for your participation; \$50 at the beginning and \$100 after you complete the study.
- You will be provided a copy of this consent form.
- Taking part in this research project is voluntary. You and your child don't have to participate, and you can stop it any time.

Why are you and your child being asked to be in this research study?

You are being asked to participate because you are at least 18-years old and have a child between 2 and 5-years old.

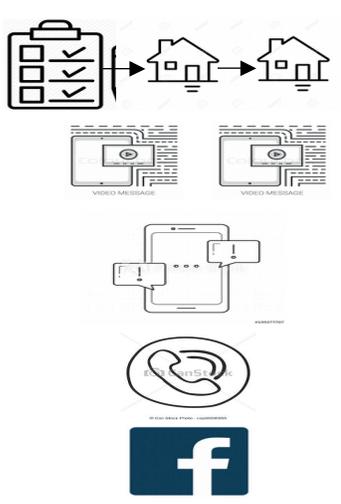
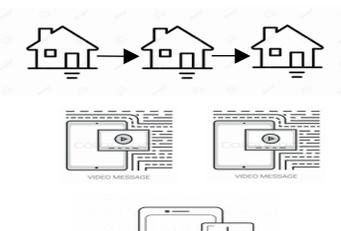
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What is the reason for doing this research study?

It is important to develop programs that may help families raise healthy children. This study will tell us how well these programs work.

What will be done during this research study?

The project will last for six-months. It 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. We will also measure your and your child's height and weight. Within a week after the visit, we will call you to ask what your child ate. This phone call will last approximately 10-15 minutes.  <p>At the end of this visit, we will “flip a coin” to see what group you will be participating in: Group 1: Feeding your child, OR in Group 2: Reading Readiness.</p>
<p>Group 1: Feeding your Child Group</p> 	<p>If you end up in this group, you will get:</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 you make cooking and eating healthy easier! ➤ For two 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. ➤ During the last three months of the study you will receive newsletters and phone calls once a month. ➤ You may also choose to part of a closed study Facebook page to connect with study staff and other parents.
<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



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	<p>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.</p> <ul style="list-style-type: none"> ➤ For two 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 newsletters and phone calls once a month.
<p>Final Home Visit: Measurements</p> 	<ul style="list-style-type: none"> • Like the first home visit, you and your child will participate in another final 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 and weight. • We call you within one-week of the visit to ask what your child ate. This call will last about 10-15 minutes.

How will my data be used?

You and your child's data will be collected on Ipads using a secure program that only certain study personnel can access. We will also be audio recording the home visit and the phone calls, for quality control purposes. 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. Your data will only be identified with an ID number.

What are the possible risks of being in this research study?

Risks or discomforts from this research study are minimal. You or your child may feel uncomfortable taking videos of your family eating or reading. You or your child may also feel uncomfortable having weight measurements recorded or having research staff come in to your home.

What are the possible benefits to you?

You and your family may learn some skills that could help you be healthier or help your children become ready to read. But you may not get any benefit from being in this research study.

What are the possible benefits to other people?

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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.

What will being in this research study cost you?

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

Will you be paid for being in this research study?

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 final measurement visit (\$75 after the home visit and \$25 after the phone call to find out what your child ate). 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.

What should you do if you or your child have a problem during this research study?

Your welfare and that of your child is the concern of all research team members. If you have a 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.

How will information about you be protected?

Reasonable steps will be taken to protect your privacy and confidentiality of your and your child's study data. The data will be stored electronically through a secure server. It will only be seen by the research team during the study and for five years after the study is complete.

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. 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.

What are your rights as a research subject?

You may ask any questions about this research and have those questions answered before or during the study. For study related questions, please contact the investigator(s) listed at the beginning of this form.

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For questions concerning your rights or complaints about the research contact the Institutional Review Board (IRB) or Vice President for Research and Economic Development:

- IRB: (401) 874-4328 / researchintegrity@etal.uri.edu.
- Vice President for Research and Economic Development: at (401) 874-4576

What will happen if you decide not to be in this research study or decide to stop participating once you start?

You or your child can decide not to be in this research study. Or, you can stop being in this research study (“withdraw”) at any time before, during, or after the research begins for any reason. Deciding not to be in this research study or to withdraw will not affect your relationship with the investigators or with the University of Rhode Island.

You or your child will not lose any benefits to which you are entitled.

Documentation of informed consent

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.

Parent Participation

Participant Name:

(Name of Participant: Please print)

Participant Signature:

Signature of Research Participant

Date

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Child Participation

Participant Name (Child's Name):

(Name of Participant: Please print)

Parent's Signature:

Signature of Parent (on behalf of child)

Date

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.

Signature of Person Obtaining Consent

Date

VIDEO ADDENDUM TO THE CONSENT FORM FOR RESEARCH

By signing this consent form, I confirm that I give my permission for video recording(s) of me and my child or family, to be used for the purposes listed above, and to be retained for five years.

Printed Name of Participant

Signature of Participant

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date