

Title: Fresh Fruits and Vegetables for Families (Fresh Families) Study

NCT #: NCT05502757

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Consent for Research Participation

Research Study Title: Fresh Fruits and Vegetables for Families (or Fresh Families) Study

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Why am I being asked to be in this research study?

We are asking you to be in this research study because you have a child living in your house between the ages of 4 and 17 years who does not meet current recommendations for fruit and vegetable consumption.

What is this research study about?

The purpose of this study is to see which fruit and vegetable provision program, paper vouchers or home delivery, best increases fruit and vegetable availability at home and child intake.

How long will I be in the research study?

If you agree to be in the study, your participation will last approximately 8 weeks. It will involve 2 assessments during which you complete online questionnaires, one before the program and one in week 5 of the fresh fruit and vegetable provision program. You will receive a fruit and vegetable provision program for 6 weeks. The program also includes one appointment to collect height and weight measures at your home.

What will happen if I say “Yes, I want to be in this research study”?

If you agree to be in this study, we will ask you to complete some online questionnaires at two different times: once before the program and again in the fifth week of the fruit and vegetable provision program. The questionnaires will ask about you and your child (age, race, etc.), food purchasing and household food availability, and your child’s fruit and vegetable intake (if your child is at least 13 years old, he/she will complete this questionnaire him/herself with your help). At the end of the study, you will also be asked about barriers to eating fruits and vegetables and your satisfaction with the program. It will take you about 20 minutes to complete the questionnaires.

Following completion of the first online questionnaire, you will be assigned by chance to one of two programs that provides 6 weeks of fruit and vegetable provisions: paper vouchers or home delivery. Over Zoom, research staff will inform you of your group assignment and provide you with instructions for how to obtain fruits and vegetables based on your program. It should take about 25 minutes to provide the instructions to you.

If you are in the paper voucher program, you will receive 6, \$15 paper vouchers (\$90 total) for purchasing fresh fruits and vegetables at the 1950 Western Avenue Food City grocery store. The vouchers will be good for 6 weeks and then expire. Each paper voucher will be good for one purchase of fresh fruits and vegetables totaling up to \$15, and then the voucher will be void. You can choose how to use the vouchers for what is best with your family for purchasing fruits and vegetables (e.g., use all vouchers at once, use one voucher a week, etc.). A store manager will need to sign off on vouchers at the time of use. You will receive text messages at the end of weeks 1-5 to remind you to use the vouchers. At the end of week 5, the text will also include a reminder that the vouchers expire in one week.

If you are in the home delivery program, you will be able to order on-line up to \$90 in fresh fruits and vegetable from the Western Ave Food City grocery store to be delivered to your home by research staff. You can choose how to use the \$90 for what is best with your family for purchasing fruits and vegetables (e.g., use all \$90 at once, use \$15 a week, etc.). Each week, you will receive a text message with available time slots for fruit and vegetable delivery, as well as what your remaining balance is for purchasing fresh fruits and vegetables. You will confirm your preferred delivery time via text and must send a response text by close of business (5:00 PM) on the day prior to delivery to indicate your online order is complete and ready for review. When ordering online, you will provide a list of preferred fruits and vegetables that can be substituted for any out-of-stock items at the time of purchase. You will be encouraged to include a note to the Food City shopper in your online orders that includes this preferred substitutions list, as well as a request that substitutions be made in the same dollar amount as the out-of-stock items. You will receive one text message the morning of your fresh fruit and vegetable delivery. This text message will confirm the scheduled delivery time. Good faith efforts will be made to hand off the fresh fruits and vegetables to you in-person. However, if you are not home at the time of delivery, the produce will be left in cold storage bags on the front porch. At the end of week 5, the weekly text will also include a reminder that the \$90 will expire in one week if you have not spent the \$90 on fresh fruits and vegetables.

Both programs will be subject to a \$15-increment rule. In other words, unused funds to the nearest \$15-increment will be considered lost. For example, if a \$14 purchase is completed, the remaining \$1 will be considered lost.

To get you started in your program, two days after you complete the online questionnaires, we will do a home visit to drop off instructions, nutrition education materials, and vouchers or information on how to access an online Food City account maintained by the research staff. We will also attempt to collect height and weight measures for you and your child at this same home visit. If we can't collect these measures at this home visit, an additional home visit will be scheduled for these measures, with this visit occurring within two weeks of when you completed the online questionnaires. This home visit will take about 10 minutes.

During the fifth week of the program, you will also be sent a link to complete the online questionnaires again.

What happens if I say “No, I do not want to be in this research study”?

Being in this study is up to you. You can say no now or leave the study later. Either way, your decision won't affect your relationship with the researchers or the University of Tennessee.

What happens if I say “Yes” but change my mind later?

Even if you decide to be in the study now, you can change your mind and stop at any time. If you decide to stop before the study is completed, you may contact the Healthy Eating and Activity Lab at 865-974-0752 to let us know that you would no longer like to participate. Any of your information already collected for the research study will be returned to you if you request it.

Are there any possible risks to me?

It is possible that someone could find out you were in this study or see your study information, but we believe this risk is small because of the procedures we use to protect your information. These procedures are described later in this form.

Are there any benefits to being in this research study?

You and your child may begin to more closely meet recommended guidelines for eating fruits and vegetables by participating in this study. Additionally, your participation may also help us to learn more about which food distribution option (food voucher or home food delivery) is best for families with children not meeting fruit and vegetable intake guidelines. We hope the knowledge gained from this study will benefit others in the future.

Who can see or use the information collected for this research study?

We will protect the confidentiality of your information by removing any identifying information that would connect you to your data and responses. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information or what information came from you. Although it is unlikely, there are times when others may need to see the information, we collect about you. These include:

- People at the University of Tennessee, Knoxville who oversee research to make sure it is conducted properly.
- Government agencies (such as the Office for Human Research Protections in the U.S. Department of Health and Human Services), and others responsible for watching over the safety, effectiveness, and conduct of the research.
- If a law or court requires us to share the information, we would have to follow that law or final court ruling.

What will happen to my information after this study is over?

We will keep your information to use for future research. Your name and other information that can directly identify you will be kept secure and stored separately from your research data collected as part of the study

We may share your research data with other researchers without asking for your consent again, but it will not contain information that could directly identify you.

Will I be paid for being in this research study?

Participants will receive a \$15 gift card after completing all follow-up questionnaires. Participant name and address will be collected to assure proper delivery of the gift card.

In addition, you will receive either fresh fruit and vegetable vouchers or home delivery of fruits and vegetables as part of the study. Families receiving both fruit and vegetable vouchers and home deliveries can receive up to \$90 worth of fresh fruits and vegetables during the 6-week program.

Will it cost me anything to be in this research study?

The only cost to you for this study is money spent on transportation to and from the grocery store if you are in the paper voucher group. Additionally, your cell phone carrier may charge standard message rates and data charges to receive text messages or reply to them.

What else do I need to know?

About 60 families will take part in this study.

We may need to stop your participation in the study without your consent if you no longer meet the study's eligibility requirements or if the study is stopped for any reason.

If we learn about any new information that may change your mind about being in the study, we will tell you. If that happens, you may be asked to sign a new consent form.

At the completion of the study, results will not be automatically disclosed to participants.

The University of Tennessee does not automatically pay for medical claims or give other compensation for injuries or other problems.

Who can answer my questions about this research study?

If you have questions or concerns about this study, or have experienced a research related problem or injury, contact the researcher, Dr. Hollie Raynor at 865-974-9126, ext. 1 or hraynor@utk.edu.

For questions or concerns about your rights or to speak with someone other than the research team about the study, please contact:

Institutional Review Board
The University of Tennessee, Knoxville
1534 White Avenue
Blount Hall, Room 408
Knoxville, TN 37996-1529
Phone: 865-974-7697
Email: utkirb@utk.edu

STATEMENT OF CONSENT

I have read this form and the research study has been explained to me. I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to contact. By signing this document, I am agreeing to be in this study. I will receive a copy of this document after I sign it.

Name of Adult Participant

Signature of Adult Participant

Date

Researcher Signature (to be completed at time of informed consent)

I have explained the study to the participant and answered all his/her questions. I believe that he/she understands the information described in this consent form and freely consents to be in the study.

Name of Research Team Member

Signature of Research Team Member

Date

IRB NUMBER: 22-0698X
IRB APPROVAL DATE: 10/18/2022
Page 4 of 4
IRB EXPIRATION DATE: 06/28/2025