

Title: Assessment of a Fruit and Vegetable Prescription Program for Children

ClinicalTrials.gov ID: NCT04767282

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CONSENT TO PARTICIPATE IN RESEARCH
Innovative Nutrition Practices in Pediatric Health Care: Assessment of a Fruit and Vegetable Prescription Program for Children in Need

Principal Investigator:

Amy Saxe-Custack, PhD, MPH, RD
Assistant Professor, Department of Food Science and Human Nutrition
Michigan State University
200 E 1st Street, Room 305
Flint, MI 48502
(810) 600-5656
saxeamym@msu.edu

Sponsor:

Michigan State University

INVESTIGATORS' STATEMENT

We are asking you and/or your child to be in a **research study**. The purpose of this consent form is to give you and your child the information you will need to help decide whether or not to be in this study. Please read the form carefully. You and your child may ask questions about the purpose of the research, what we would ask you and your child to do, the possible risks and benefits, you and your child's rights as a research participant, and anything else about the research or this form that is not clear. When all your questions have been answered to you and your child's satisfaction, you and/or your child can decide to be in the study or not. This process is called informed consent.

SITE OF THE RESEARCH STUDY

The study will be conducted at Hurley Children's Center, Akpinar Children's Clinic, Mott Children's Health Center, or remotely through telephone or online survey link sent through text message or email.

1. PURPOSE OF STUDY

- This is a research activity of the impact of a fruit and vegetable prescription program for children. You and/or your child are being asked to participate because your child is a patient at Hurley Children's Center, Akpinar Children's Center or Mott Children's Health Center and has received a fruit and vegetable prescription.
- From this study, the researchers hope to learn the impact of the fruit and vegetable prescription program on diet and weight, food security, and access to fresh foods.
- You and/or your child's participation in the study will take about 30 minutes. We will ask you and your child to complete some paperwork one time only if your child is a patient at Hurley Children's Center or Akpinar Children's Center. If your child is a patient at Mott Children's Health Center, we will ask you and your child to return to the clinic to complete the surveys every six months for two years (a total of five separate visits). You will receive a gift card with each completed appointment.
- We will partner with Flint Farmers' Market and Flint Fresh on this project. You may redeem the prescriptions at either site, including on-line or telephone ordering of Flint Fresh Veggie Boxes. In addition to a series of survey questions about the impact of the prescriptions, we will also ask about your personal experiences with each of our partners.

2. WHAT YOU AND/OR YOUR CHILD WILL DO

- You and your child have been selected to participate in a survey with a researcher to help us understand the impact of the fruit and vegetable prescription program on diet, weight, food access, and food security. We will also ask you and your child to describe your experiences with program. You and your child will help researchers determine whether the prescription program offered through Hurley Children's Center, Akpinar Children's Clinic, and Mott Children's Health Center can help improve eating behaviors of children and families.
- Researchers will collect baseline survey data from approximately 850 families (one child and one caregiver per family) from approximately February 2021 through September 2021.
- If your child is a patient at Hurley Children's Center or Akpinar Children's Clinic, you and your child will complete these forms, and your child's weight and height will be measured one time only. If your child is a patient at Mott Children's Health Center, a research assistant will complete the surveys with you and your child, measure your child's weight and height, and schedule four more visits (every 6 months) at a time that is convenient. She will contact you and your child to remind you of scheduled in-person or remote interviews.
- We will ask you and your child to complete a series of questions about fruit and vegetable intake, access to fresh foods, and feelings about food insecurity.
- We will ask you and your child (with the help of a research assistant) to complete dietary information, food insecurity information, and a survey about fruits and vegetables.
- We would like to measure your child's weight and height. If unable to measure in-person, then we will review your child's medical chart for height and weight and ask you for these measures.
- We would also like to review your child's medical chart and record the number of prescriptions your child has received since the fruit and vegetable prescription program was introduced at his/her pediatric clinic, his/her height and weight, blood pressure, and glycemic control.
- If your child is a patient at Mott Children's Health Center, future meetings will last approximately 30 minutes and will be held in-person at Mott Children's Health Center or remotely. In addition to asking the same survey questions, we will ask you to talk about your experiences with the prescription program at one-year and two-year follow-up. This will help researchers modify and improve the programs.
- The brief interviews will occur after you and your child have completed the survey questions at one-year and two-year follow-up and will ask about experiences, likes/dislikes regarding the program, information you and your child may have learned, and suggestions for improvement.
- Your participation is voluntary, and you and your child may stop participating at any time.
- You and your child may skip any questions that you do not wish to answer.

- You and/or your child may choose how much information you feel comfortable sharing, and your identity will not be shared with anyone.
- Researchers would like to audiotape only the interview portion at the one-year and two-year discussion. We will destroy the recording after the information has been written down and all names will be deleted from transcripts.

3. BENEFITS

- There are no anticipated direct benefits to you and/or your child for participating in this study, but the study may assist researchers in improving the nutrition programs offered through Hurley Children's Center, Akpinar Children's Clinic, and Mott Children's Health Center.

4. POTENTIAL RISKS

- There is a risk of medical and other research data leak.

5. PRIVACY AND CONFIDENTIALITY

- The data for this project will be kept confidential, and you and your child's name will not be shared with anyone.
- Audio recordings of the interviews at one and two years are optional, and pseudonyms will be used in the transcripts to protect the identities of all participants. Audio devices will be stored in a locked file cabinet, and all audio recordings will be erased after transcripts are complete and checked for accuracy. All recordings will be erased by August of 2024.
- Interviews will be held over the phone or in a room where only the participants and one researcher will be for the duration of the interview.
- Only the research team and Michigan State University Human Research Protection Program will have access to the research records.
- The final de-identified dataset will be shared with a National Institutes of Health-supported data repository. This dataset will be removed of all identifiers. Information will be shared only under a strict data-sharing agreement that provides for: (1) a commitment to using data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed.
- Information that identifies you/your child (such as name and address) will be removed from the data set. After such removal, information related to food security, food access, physical activity, sleep or diet could be used for future research studies without additional informed consent from you/your child.
- All data will be stored on a password protected computer.
- Research data will be stored for 3 years after the close of the research study. All identifiable data will be destroyed after that time.

- In the writing of any results, pseudonyms will be used.
- A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. 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 the web site at any time.
- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

6. VOLUNTARY PARTICIPATION AND WITHDRAWAL

- Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you and your child are otherwise entitled. You and your child may discontinue participation at any time without penalty or loss of benefits to which you and your child are otherwise entitled.
- Participation in the research study will in no way impact your child's eligibility to receive a fruit and vegetable prescription.

7. COSTS AND COMPENSATION FOR BEING IN THE STUDY

- You and your child receive one \$15 electronic gift card for participation in surveys now.
- You and your child receive one \$10 electronic gift card for participation in a second dietary recall.
- If your child is a patient at Mott Children's Health Center, a \$15 electronic gift card will be provided at 6-month data collection. One \$40 electronic gift card will be provided at 12-month follow-up data collection. One \$40 electronic gift card will be provided at 18-month follow-up data collection. One \$50 electronic gift card will be provided at the final 24-month follow-up data collection.
- After each 6-month data collection, a \$10 electronic gift card will be provided for child's participation in a second dietary recall.
- Gift cards will be provided even if you or your child decline to answer some of the questions.

CONTACT INFORMATION

In the event of a research-related concern, please immediately contact one of the investigators listed. Also, if you and/or your child have any questions about the research, please feel free to contact Amy Saxe-Custack (Assistant Professor, Division of Public Health, College of Human Medicine, Michigan State University, (810) 600-5656).

SUBJECT'S STATEMENT

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions and all my questions have been answered to my satisfaction. If I have questions later on about the research, or if I experience a research-related injury, I can call one of the investigators listed above.

If you and/or your child have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or email irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing MI 48910.

the use of a secure system for electronic or digital signature that provides an encrypted identifiable 'signature.' If properly obtained, an electronic signature can be considered an 'original' for the purposes of recordkeeping.

I give consent to be audiotaped during this study:

Please initial: ____Yes ____No

Name of Subject (Print)

Signature of Assenting Child (13-18 Yrs of Age)

Date

Signature of Subject/Parent/Legal Guardian

Date

Address of Subject/Parent/Legal Guardian

Innovative Nutrition Practices in Pediatric Health Care: Assessment of Fruit and Vegetable Prescriptions for Children in Need

Person leading the study: Amy Saxe Custack, PhD, MPH, RD

Why are we doing this research?

The reason we are doing this research is to understand whether the fruit and vegetable prescriptions help kids eat healthier.

Why are you being asked to participate in this research study?

The reason you are being asked to participate in the study is because you are a patient at one of three clinics in Flint that offer a fruit and vegetable prescription program to all of their patients.

What will happen during the study?

You will be asked to fill out an on-line survey and, if in-person, a research assistant will measure your height and weight. The survey will take about 30 minutes to complete and will ask you about your eating habits. If you are a patient at Mott Children's Health Center, we will ask you to come back to the office four more times (once every six months) to complete the survey again and have your weight and height measured.

Risks and Benefits?

We do not anticipate any potential problems.

Who will be told the things we learn about you in this study?

Only the research team will have access to the information collected. Your name will not be in any report of the results of this study.

Will there be any money or gifts for participating?

Your parents will receive a \$15 electronic gift card for participating in the study and an additional \$10 electronic gift card for a second dietary recall that you will be asked to complete a few days after the survey. If you are a patient at Mott Children's Health Center, your parents will receive electronic gift cards when you complete the surveys again remotely or in the clinic at 6-months (\$15), 12-months (\$40), 18-months (\$40), and 24-months (\$50). After each 6-month survey completion, your parents will receive an additional \$10 electronic gift card if you complete a second dietary recall.

What if you or your parents do not want you to be in this study?

You can only participate if both you and your parents agree for you to be in the study. Nobody will be upset if you do not want to be in the study. It is your decision. If you decide to be in the study, and later change your mind that is okay too. You can stop being in the study anytime you like.

What if you have any questions about the study?

If you have any questions about the study, you can either tell your parents and have them talk to me or talk to me yourself. Here is my phone number and address: (810)600-5656; Michigan State University Division of Public Health 200 E 1st Street Flint, MI 48502.

Documentation of Assent

If you sign your name on this page, it means that you agree to take part in this research study. You may change your mind at any time

Name: _____ **Date:** _____