

RESEARCH CONSENT FORM

Basic Information

Title of Project: Comparative Effectiveness of Two Interventions to Reduce Food Insecurity during the COVID-19 Pandemic

IRB Number: H-41052

NCT: NCT04652596

Sponsor: Patient-Centered Outcomes Research Institute (PCORI), United States Department of Agriculture (USDA), Krupp Family Foundation, Waldron Foundation

Principal Investigator: Caroline Kistin, MD, MSc
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Study Phone Number: 617-414-3642

Overview

We are asking you to be in a research study to determine the best ways to help BMC families with young children address concerns about the availability of food. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. If you agree, you will be assigned to one of two groups.

- Group 1: Participants in this group will receive a stipend each month for 6 months to shop at mobile farmers markets that sell fruits, vegetables, and other fresh foods in communities around Boston.
- Group 2: Participants in this group will receive grocery store gift cards each month for 6 months.

Both groups will have interviews that will happen every month for 12 months over the phone or on zoom. You will be in the study for 12 months if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are:

1. Feeling uncomfortable or emotionally distressed when being asked questions about your and your family's health, food security status, depression, or other sensitive topics;
2. Making changes to your schedule to fit in future meetings with the study. You will find more information about risks later in this form; and
3. Loss of confidentiality.

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You might benefit from being in the study because you will receive a total of \$150 per month, for 6 months, in the form of either a grocery store gift card or a stipend to shop at mobile markets. You will find more information about benefits later in this form.

You could get benefits without being in the study through Project REACH, an outreach program in the Department of Pediatrics that connects families to a variety of services at BMC. You will find more information about alternatives later in this form.

Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. Your doctor's goal as an investigator is to collect information to answer the scientific questions asked in this research study, in order to help future patients. This is different from their role as your doctor, where their goal is to treat you as a patient. You may want to get another opinion about being in the study from a doctor who is not an investigator in this study. You can do so now or at any time during the study. You do not have to agree to be in this study even though it is offered by your doctor.

Purpose

We are trying to determine the best ways to help BMC families address concerns about the availability of food. We are studying if grocery store gift cards and mobile farmers markets stipends can help families increase food security, reduce unnecessary healthcare visits, and positively impact physical and emotional health.

What Will Happen in This Research Study

All or part of the research in this study will take place over the telephone or zoom if you prefer.

If you choose to be in this study, we will ask these things of you:

1. We will ask you to complete the first telephone interview, which takes about 60-90 minutes. After you complete the interview, we will give you a \$30 BMC Clincard to compensate for your time in completing the first research interview.
2. After the first interview, you will be randomized into one of two groups. Randomization means that some participants in the study will be assigned to one group. Other participants will be assigned to another group. This randomization is done by chance, like flipping a coin. You will not have a choice as to which group you are in. Randomization is done so the researchers can see if there is a difference between the two groups.
 - a. One group will receive a \$150 stipend card each month, for 6 months, that will allow them to purchase fruits and vegetables at mobile markets in communities throughout the Boston area. The mobile markets include a truck that travels into communities selling fresh fruits and vegetables and some farmers markets around Boston.
 - b. The other group will receive \$150 in grocery store gift cards each month for 6 months.
3. We will ask you to complete an interview each month, over the next 12 months. These interviews take about 45 minutes on average. The interview questions will be about the types of

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foods you have access to, what foods you usually eat, physical and emotional health, your social supports, your experiences as a mother, and your family's experience during the COVID-19 pandemic. You do not have to answer any question that you don't feel comfortable answering. We will periodically ask you about any planned or unplanned time away from the Boston area that would make it difficult for the study staff to stay in touch with you.

4. At some of your interviews, you will be asked questions about your safety, and whether or not you have thought about hurting yourself or ending your life. If this is the case, we will take actions to try to help keep you safe. We may contact a mental health worker on an emergency basis to connect you with hospital-based emergency services.
5. We will collect some data from your medical record and health insurance. This includes information about your scheduled doctor's appointments and hospital visits; information on housing, food, and employment status; and some claims data.
6. We will collect some data from your child's medical record to look at things like scheduled doctor's appointments, information on weight and height, and whether or not he/she has received certain services (like immunizations).
7. We would like to stay in contact with you during the study. We will ask you to provide the names and telephone numbers of three family members or friends who would know how to contact you if we lose touch with you during the study. We may also search for contact information by checking in both your and your child's record at Boston Medical Center. This would allow us to see if your updated contact information is listed. We encourage you to contact us each time your contact information changes.
8. If you receive the mobile market group, we need to share information about with the community partner who operates the mobile farmers markets. The community partner needs information that identifies you so that you can be assigned a stipend card and have access to the mobile markets and programs the community partner provides. We will share your name, address, email, phone number, language, date of birth, race/ethnicity, household size, and if you participate in programs like SNAP.
9. If you receive the mobile market group, the company that owns and runs the mobile market may contact you from time to time to ask you questions. The company may call you to ask why you have or have not shopped at a mobile market and what you like or dislike about the markets. They might also contact you to tell you about optional events that you could attend, like special pop-up markets or food demonstrations.
10. If you receive the mobile market group, we will look at things like how frequently you shopped at the mobile markets and what you bought.
11. If you receive the mobile market group, we will share information with organizations who fund the research or help oversee the research. The information we share will not have your name attached to it.

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The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

You will be one of approximately 250 subjects who will be asked to be in the study.

Risks and Discomforts

You may experience emotional distress or discomfort when talking about stress, depression, parenting challenges, health, food security status, and emotionally sensitive subject matters. You will have a series of over-the-phone, confidential interviews with a member of the research team who has trained in human subject and confidentiality issues. In addition, participations will require your time and may disrupt your usual schedule.

To address the risks described above, the following steps will be taken:

1. You can stop the study at any time.
2. You can choose not to answer any questions during the study.
3. You will be provided with the study team's phone number and will be given the opportunity to talk about any concerns or questions with study personnel at any point.

Potential Benefits

You might benefit from being in the study because you will receive a total of \$150 per month, for 6 months, in the form of a grocery store gift card or a stipend to shop at mobile markets. However, you may not receive any benefit.

Your being in the study may help the investigators learn ways to help BMC families access and eat more fruits and vegetables during the pandemic.

Alternatives

The following alternative procedures or treatments are available if you choose not to be in this study:

One of your alternatives is not to participate in this study.

Another alternative is to request that Project REACH assist you in accessing services. You can get services to help you without being part of this research study.

Costs

There are no costs to you for being in this research study.

Payment

You will receive \$30 on a BMC Clincard to compensate for your time in completing the first research interview. The BMC Clincard is a web-based reloadable debit card program; you will use the same card

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throughout the study. For the 1 to 6-month interviews, you will be compensated with \$10 on your BMC Clincard for each interview you complete. For the 7 to 11-month interviews, you will be compensated with \$23 on your BMC Clincard. For the final 12-month interview, you will be compensated with \$35 on your BMC Clincard.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

If you agree to be in the study, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- People who will get information from us, specifically those at Fresh Connect mobile markets as described above in the What Happens section. These people are expected to protect your information in the same way we protect it.
- Any people who you give us separate permission to share your information.

You should know that we are required to report information about suspected child abuse or neglect or if we are worried that a participant wants to hurt themselves or others.

If you are in immediate danger of hurting yourself at any time in the study, the study team will try to work with you on a plan to keep you safe. Because study staff will be trying to protect you, it is possible that your information will be shared with others as part of a plan for safety.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. 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 this Web site at any time.

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Use and Sharing of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this research includes:

- Information that is in your hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The reasons that your health information might be used or shared with others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- If you receive the mobile market group: to share your information with a community partner so that you can be assigned a stipend card and have access to the mobile markets and other food-related programs and resources the community partner provides.
- To comply with laws and regulations. This includes safety-related information. As we explained above, we also have to share any information from you about suspected child abuse or neglect or if we are worried that a participant wants to hurt themselves or others.
- To protect you. As we explained above, if you are in immediate danger of hurting yourself, it is possible that your information will be shared with others as part of a plan for safety.

The people and groups that may use or share your health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
- The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research
- Public health and safety authorities who receive our reports about suspected child abuse or neglect or if we are worried that a participant wants to hurt themselves or others.
- Other care providers and public safety authorities who may be involved in helping to protect you if you express thoughts about hurting yourself.

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We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at DG-privacyofficer@bmc.org.

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please indicate your choice below:

____ Yes ____ No You may contact me again to ask for additional information related to this study

____ Yes ____ No You may contact me again to let me know about a different research study

Upon completion of the entire study in approximately 3 years, we would like your permission to send you a synopsis of the research study findings. There will be no information to identify any of the study participants but will include a summary describing the results of the study.

_____ I give permission to be sent a copy of the study summary.

_____ I do NOT give permission to be sent a copy of the study summary.

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Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study, you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get. You will only be paid for the study activities that you complete before withdrawing.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Jocelyn Antonio at 617-414-3828. Also call if you need to report an injury while being in this research.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described, including your health information.

Signature of subject

Date