A Trial of Behavioral Economic Interventions Among Food Pantry Clients

NCT04011384

2021-12-17

Consent Form

University of Pennsylvania
Concise Summary

Title of the Research Study: Consumer Research on Food Pantry Ordering System

Protocol Number: 829702

Principal Investigator (PI): Christina A. Roberto; 423 Guardian Drive, Blockley Hall, Philadelphia, PA 19104; 215-746-7064; croberto@pennmedicine.upenn.edu

Emergency Contact: Abeselom Gebreyesus; 423 Guardian Drive, Blockley Hall, Philadelphia, PA 19104; 215-746-6476; abeselom.gebreyesus@pennmedicine.upenn.edu

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You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to learn more about your food pantry ordering preferences and experiences. You are eligible to participate because (1) you are over 18 years old, (2) you're the primary grocery shopper for your family, (3) you receive food from the food pantry at least one time every month, (4) you are willing and able to place orders online yourself or with assistance while still viewing the screen, (5) you are willing and able to use a blood pressure cuff and scale we provide to you.

If you agree to join the study, you will be asked to shop using the food pantry's online ordering system each month over the course of four months. We will also ask you to meet with us at two time points to take several brief surveys and have your height, weight, blood pressure, and diet quality measured. Your participation will last for about four months.

There are no direct benefits of your participation in this study, although we will provide you with the results of your blood pressure measurements. Additionally, you will be contributing to generalizable understanding of client experiences at food pantries. This study has minimal risks. The most common risk of participation is breach of confidentiality. We take efforts to minimize this risk, so that only researchers involved in this study and those responsible for research oversight will have access to the identifiable information provided. The alternative to participating is not participating, and there is no penalty or loss of benefits if you choose not to participate.

Please note that there are additional factors to consider before agreeing to participate, such as use of your personal information and payment that are not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

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You are being asked to take part in a research study. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you decide, you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if you decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to decide now; you can take the consent document home and share it with friends, family doctor and family.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

What is the purpose of the study?

The purpose of the study is to learn more about your food pantry ordering preferences and experiences.

Why was I asked to participate in the study?

You are being asked to join this study because (1) you are 18 years of age or older, (2) you are the primary grocery shopper for your household, (3) you receive food from the food pantry at least one time every month, (4) you are willing and able to place orders online yourself or with assistance while still viewing the screen, (5) you are willing and able to use a blood pressure cuff and scale we provide to you. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How long will I be in the study?

The study will take place over a period of four months. In addition to shopping online each month, study staff will meet with you twice, once in the next few weeks and once at the end of the study, to ask you to participate in surveys and physical measurements.

How many people will take part in this research?

About 500 people will take part in this research.

Where will the study take place?

The study will take place at the Jewish Federation KleinLife Food Pantry located at 10100 Jamison Ave, Philadelphia, PA 19116. During the COVID-19 pandemic, we will ask you to complete surveys and physical measurements in your home and just outside your home, with the guidance of a research assistant.

What will I be asked to do?

You will shop using the food pantry's online ordering system each month over four months. When you successfully place an online order (i.e. you selected the food while viewing the screen yourself), you will receive $5 for your baseline order, $3 in the second month, $3 in the third month, and $4 in the fourth month, totaling $15 over the course of the study.

Upon first enrolling in the study, study staff will ask you some questions about yourself. Next we will walkthrough the pantry online ordering system with you. You will receive $25 for completing this training. This means that we will set up a time to meet at the Pantry or over the phone to teach you how to use the system. This will take about 20-30 minutes. We will then set up a time to meet with you to do physical measurements and surveys. You will receive $25 for completing the surveys and having height, weight, blood pressure, and diet quality measured by study staff.

Three months later, you will be asked to complete a survey and have your weight, blood pressure, and diet quality measured a second time. Again, you will receive $25 for completing the surveys and measurements.

What are the risks?

This study poses minimal risks. Potential risks include breach of confidentiality. We aim to minimize this risk. Only the researchers involved in this study and those responsible for research oversight will have access to the identifiable information provided.

What are the risks related to COVID-19?

You will be having in-person visits with researchers which may increase your risk of being exposed to and spreading SARS-COV-2, the virus that causes COVID-19 disease. Coronavirus disease 2019 (COVID-19) is a new illness caused by a novel (previously unidentified) coronavirus (SARS-COV-2). Physical distancing, wearing a face mask, and hand-washing are the primary strategies used to prevent the spread of the virus. Penn research personnel will follow the Centers for Disease Control and Prevention (CDC) recommended steps designed to minimize spread of the virus. We will ask you to follow these guidelines during visits with study staff. This may include asking you to come outside for physical measurements and performing physical measurements (weight and blood pressure) yourself with verbal assistance by study staff.

If you contract the virus, you may not experience any symptoms. Because this is a novel virus there may be symptoms that we do not know about. The most frequently experienced symptoms are cough, fever, and shortness of breath. These symptoms range from mild to severe illness; the latter may lead to pneumonia and death. Symptoms typically appear 2-14 days after exposure to the virus.

There are certain high-risk groups that are more at risk for severe illness including those with chronic kidney disease, COPD (chronic obstructive pulmonary disease that includes conditions such as asthma and emphysema), weakened immune systems, organ transplant recipients, obesity, serious heart conditions, sickle cell disease, and type 2 diabetes.

Some children who have been exposed to the virus develop Multisystem Inflammatory Syndrome (MIS-C), a condition in children where different body parts and organs can become inflamed. MIS-C can be serious and may lead to death. Symptoms may include, but are not limited to, fever, abdominal pain, vomiting, diarrhea, neck pain, rash, fatigue, and bloodshot eyes.

For the most up to date list of all possible COVID-19 and MIS-C symptoms, please refer to the CDC website: https://www.cdc.gov/coronavirus/2019-nCoV/index.html or contact your primary care physician. Not everyone experiences the same symptoms. Contact your primary care physician if you are experiencing symptoms that are concerning to you. Call 911 if you are experiencing trouble breathing, pain or pressure in your chest or abdomen, or bluish lips, face, or toes.

Please inform the study team if you have any of these symptoms. Please inform the study team if you develop any of these symptoms or have a positive COVID-19 test within 2-14 days of an in person visit with the study team. If you are an individual that is part of a high-risk group as defined by the CDC, please inform the study team. We may ask you a series of COVID-19 screening questions prior to in-person study visits.

If you feel as though the CDC guidelines are not being followed during your research visits, please talk with the study staff, submit an anonymous complaint through Ethics Point by calling 215-726-6759, or reach out to the Penn IRB at 215-898-2614. Please discuss with your study team, ask all questions you may have.

How will I benefit from the study?

There are no direct benefits of your participation in this study, although we will provide you with the results of your blood pressure measurements. Additionally, you will be contributing to generalizable understanding of client experiences at food pantries.

What information about me may be collected, used or shared with others?

We will be collecting the following information about you:

- Your purchasing history from the food pantry
- Your height, weight, blood pressure, and a measure of overall diet quality
- Information about your health and diet from a self-reported questionnaire
- Some additional personal information including name, address, telephone number, and date of birth

Why is my information being used?

The research team will use your contact information to stay in touch with you during the study. Your other information and results of tests and procedures will be de-identified and grouped with all the other participants' information to understand how shopping experiences at the food pantry affect people.

What may happen to my information collected on this study?

Your information will be de-identified. De-identified means that all personal identifiers (e.g., your contact information) are removed. De-identified information could be stored and shared for future research. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future

researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your de-identified information only applies to the information collected in this study. Your information will not be used to create products that may be sold or to make money for others. 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.

How will confidentiality be maintained and my privacy be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Data collected, including your identifiable information, may be seen by the University of Pennsylvania Institutional Review Board (IRB) that oversees the research. Your personal information may be given out if required by law. We will protect your privacy by putting all identifying information on password-protected files that will be stored on password-protected computers. Only the researchers involved in this study and those responsible for research oversight will have access to the identifiable information provided. If information from this study is published or presented at scientific meetings, it will be grouped across participants. Your name and other personal information will not be used.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator of the study. If you withdraw your permission, you will not be able to stay in the study.

What if I decide not to give permission to use and give out my health information?

You will not be able to participate in this research study.

What other choices do I have?

Your alternative to being in the study is to not be in the study.

What happens if I do not choose to join the research study?

You may choose to join the study or you may choose not to join the study. Your participation is voluntary. There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you or would come to you in the future. If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

When is the study over? Can I leave the study before it ends?

The study is expected to end after all participants have completed all visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety or health – you will be informed of the reasons why
- You have not followed the study instructions
- The PI, the sponsor, or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care.

If you no longer wish to be in the research study, please contact Christina Roberto, PhD, at croberto@pennmedicine.upenn.edu.

Will I receive the results of research testing?

Most tests done in research studies are only for research and have no clear meaning for health care. The results of physical measurements from this study will be provided to you directly and will include the normal range of results when applicable. If any of your results fall outside of the desirable or normal range, you should consult with your physician.

Will I have to pay for anything?

It will not cost you anything to participate in this research.

Will I be paid for being in this study?

For completing the assessments, we will compensate you up to $90 for completing all study sessions. If you do not attend the sessions, you will not receive compensation.

The $90 will be broken up into the following payments:

- $25 for online ordering walkthrough
- $25 for baseline assessment
    - $10 for baseline surveys
    - $5 for baseline weight measurement
    - $5 for baseline blood pressure measurement
    - $5 for baseline diet quality measurement
- $25 for 3-month assessment
    - $10 for 3-month surveys
    - $5 for 3-month weight measurement
    - $5 for 3-month blood pressure measurement
    - $5 for 3-month diet quality measurement
- $5 for baseline shopping
- $3 for shopping month 1
- $3 for shopping month 2

- $4 for shopping month 3

Please note: The University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator, Christina Roberto, listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this document, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document. Please let us know if you prefer to sign a paper copy of this form rather than signing electronically.

Signature of Participant

_____

Print Name of Participant

_____

Date

_____

Participating in Future Research Studies

We would like to contact you in the future to see if you would be interested in participating in another research study. Please indicate below if you are willing to be contacted about any future research studies.

____ Yes, I agree to be contacted about future research studies.

____ No, I do not want to be contacted about future research studies.