ReCLaiMeD: Using community healthcare workers to improve blood pressure control among food insecure hypertensive adults: Aim 2

NCT05877898

February 21, 2025

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM to Participate in Research

Title of this study: ReCLaiMeD: Using community healthcare workers to improve blood pressure control among food insecure hypertensive adults: Aim 2

Researchers: Dr. Stephanie Staras, MSPH, PhD and Dr. Carla L. Fisher, PhD

You are being asked to participate in a research study.

Before you agree to take part in this study, Dr. Stephanie Staras or his/her representative will tell you:

Why the study is being done and what will happen to you if you take part in the study:

If you take part in this study, you will be randomly assigned equally (much like the flip of a coin) to one of the three study arms: (1) no strategy (n=25 participants), (2) Community health worker provided education (n=25 participants), and (3) Community health worker provided education and Navigation (n=25 participants). At the beginning and the end of the study, you will be invited to complete a brief survey about your fruit and vegetable intake and your health. We will also measure your blood pressure and use a device that measures your fruit and vegetable intake by placing one of your fingers on a lens.

If you are in no strategy arm, you will be provided a color copy of National Institutes of Health's (NIH) Healthy Blood Pressure for Healthy Hearts: Small Steps to Take Control Flyer.

If you are in the Community health worker provided education arm, you will be invited to meet with the community health worker for up to 1-hour to learn about how eating healthier can reduce your blood pressure and how to receive healthy foods locally for free or limited costs.

If you are in the Community health worker provided education and navigation arm, you will be invited to meet with the community health worker to learn about eating healthier can reduce your blood pressure and how to receive healthy foods locally for free or limited costs. The community health worker will also share with you a menu of additional options you can participate in: (1) transportation to the grocery store (weekly for 4 weeks) or $10 gas card, (2) cooking recipes made for individuals with hypertension, (3) access to University of Florida Institute of Food and Agricultural Sciences' (UF IFAS) online library of healthy food cooking videos.

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 long you will be in the study:
4 weeks

How many people will be in the study:

75 adults ages 18 to 65 years

The possible foreseeable risks, discomforts, and benefits of this research:

While there is potential risk for loss of confidentiality, appropriate steps will be taken to protect your information. Participants may benefit from learning their blood pressure, receiving education about how to control their blood pressure, and learning strategies of how to obtain and use more fruits and vegetables. Participants may lower their blood pressure.

Alternatives to being in the study:

You can choose not participate in the study. Not participating will have no effect on you or your relationship with your community, church, or the University of Florida (UF) or UFHealth.

How your study records will be maintained and who will have access:
All surveys and records of your blood pressure or from the Veggie Meter will be collected with Research Electronic Data Capture (REDCap): a secure on-line data collection system. Data will be downloaded onto UF approved PHI storage areas (UF server or UF dropbox).

If the results of this research are published or presented at scientific meetings, your identify will not be disclosed.

If it will cost you anything to take part in this study:

Participating in this study will not cost you anything.

If you will be compensated for taking part in this study:

You will be compensated with $25 for completing baseline measurements and $50 for completing the post-implementation measurements four weeks from now.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name and address is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. If you have any problems regarding your payment contact the Principal Investigator.

When or if you may be told about new findings which may affect your willingness to keep taking part in this study:

Participants will be notified in the unlikely event that their information has been compromised.

If you agree to participate in this study, you will be given a signed copy of this document.

You may contact Dr. Stephanie Staras at (877) 272-7409 at any time if you have questions about the research or if you think that you have been hurt by the research.

You may contact the Institutional Review Board at the University of Florida Health Science Center at (352) 273-9600 if you have questions about your rights as a research subject or what to do if you are injured.

You may choose not to be in this study or you may quit being in the study at any time and there will be no penalty and no loss of any benefits you are entitled to. Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise, your research records will not be released without your permission unless required by law or a court order.

Once this research study is completed, any information that could identify you might be removed from any identifiable private information collected and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

Signing this document means that the research study, including the above information, has been described to you orally and/or that you have read this document, and you voluntarily agree to take part.

_____	_____
Signature of Person Obtaining Consent	Date
_____	_____
Signature of Person Consenting	Date