Pilot Study to Evaluate the Feasibility of Using a Sequential Multiple Assignment Randomized Trial to Address Food Insecurity in Patients With Hypertension (Pilot SMART-FI)

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Wake Forest University
School of Medicine

Department/Section of *Internal Medicine*

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Informed Consent Form to Participate in Research
Deepak Palakshappa, MD MSHP, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is assisting people with better access to food improves blood pressure. You are invited to be in this study because your doctor is treating you for high blood pressure and you are a patient at Atrium Health Wake Forest Baptist. Your participation in this research will involve 3 visits (1 in person and 2 over the phone) and last about 6 months.

Participation in this study will involve having your blood pressure checked and completing surveys in-person and over the phone. Also, you may work with a Community Health Worker (CHWs). CHWs are frontline public health workers who are trusted members of and have a close relationship with the community they serve. This enables CHWs to serve as a link between health and social services. You may also receive meals from Second Harvest Food Bank. The meals are specifically designed for people who have high blood pressure. A risk to this study that you should be aware of is some of the questions may make people feel uncomfortable. While we cannot promise that you will personally benefit from this study, you may benefit by getting connected with additional resources in the community.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies help scientist learn new information that may help other people in the future. You are being asked to be in this study because your doctor is treating you for high blood pressure and you are a patient at Atrium Health Wake Forest Baptist. High blood pressure accounts for more cardiovascular disease deaths than any other cardiovascular disease risk factor. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine if different ways of helping people better access food helps with their blood pressure.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

60 people at your primary care clinic will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

At your first visit, we will check your blood pressure and ask you to complete some surveys. We will also provide you with a home blood pressure monitor. We will then randomize you to one of 2 groups. In 3 months, we will call you and ask you complete some additional surveys and check your blood pressure at that time. Depending on what your blood pressure is, we may randomize you to one of 2 additional groups. We will follow back up with you in 6 months and ask you to do the same surveys and check your blood pressure. You will be able to keep the home blood pressure monitor after the study is complete.

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin.

At the start, we will randomize you to one of 2 groups:

1. Receiving information about local community resources
2. Working with a CHW. If you are in this group, a CHW will contact you and ask some additional questions and see if there are ways they can help you access resources in the community that could help with your blood pressure or health. The frequent and amount of time of each point of contact will be at the discretion of the CHW.

After 3 months, we may randomize you again to one of 2 groups depending on what your blood pressure is.

1. Working with a CHW.
2. Receiving home delivered meals from Second Harvest Food Bank. The meals are scratched-made and designed by a nutritionist specifically for people with high blood pressure. We will deliver 10 meals a week for 3 months. The meals can be stored in refrigerator or freezer, and heated up on a stove, microwave or oven. We will need to

provide your contact information and address to people at Second Harvest in order to deliver the meals.

We can send copies of your blood pressure results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

How Long Will I Be in the Study?

You will be in the study for about *6 months*

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

As part of this study, you will be asked questions about social supports. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

Are There Benefits to Taking Part in the Study?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

What Other Choices Are There?

You do not have to be in this study. You should talk to the researchers about all the choices you

have.

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, including any study products or procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

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. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. 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.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid *$20* per study visit (Total of $60 for 3 visits. You will also be provided a home blood pressure monitor. If you withdraw for any reason from the study before completion you will be paid *$20* for each complete study visit.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by *the National Institutes of Health.* The sponsor is providing money or other support to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and information we get from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** age, gender, location, your medical problems, blood pressure, insurance, and healthcare visits.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Deepak Palakshappa that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Deepak Palakshappa, MD MSHP
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

WFU School of Medicine
Institutional Review Board
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You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, **Deepak Palakshappa at [redacted].**

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm