Informed Consent
Date:11/11/2020
Study Title: Implementing the Los Angeles Barber – Pharmacist Model of Hypertension Management in Nashville
NCT04232124

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: David Harrison, MD **Revision Date: 02/18/2020**
Study Title: Implementing the Los Angeles Barber – Pharmacist Model of Hypertension Management in Nashville
Institution/Hospital: Vanderbilt University Medical Center

This informed consent document applies to: African American/Black men between 35-79 years of age with hypertension.

Name of participant: _____ Age:_____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

What is the purpose of this study?
The purpose of this study is to establish an effective network of barbershop research hubs in Nashville. You are being asked to take part in this research study because African American/black men face a shorter life expectancy than white men because of higher prevalence and worse outcomes from many diseases; most notably high blood pressure and its related heart problems. This uniquely designed model was established in barbershops as a hub as a social setting for black men to openly discuss important issues in their lives - including health with barbers (trusted community members with a loyal clientele) and other black men. This model offers black men an opportunity to engage with a clinical pharmacist, receive regular blood pressure checks and medication monitoring to help manage their high blood pressure.

Procedures to be followed and approximate duration of the study:
You are being offered enrollment because you have participated in two screening in your barbershop and met the following criteria:

a) Adult 35-79 years old
b) Self-identify as Non-Hispanic African American/black male
c) Patron of one of the participating barbershops (>4 haircuts in the last 6 months)
d) Systolic blood pressure over 140 mmHg on two screening days at least one day apart

If you join this study you will be agreeing to visit with a study pharmacist for review and management of your blood pressure medications. The pharmacist will be supervised by either a Vanderbilt study physician or by your primary care or other physician managing your high blood pressure, if they also agree and are Vanderbilt physicians. Your study physician or pharmacist visits will be recorded in the Vanderbilt medical record in addition to the research study record. Trained barbers will frequently check your blood pressure when you get haircuts and your blood pressure readings will be sent to the study team. Barbers will also talk with you about working with the study clinical pharmacist, who will meet you in their barbershop to better manage your blood pressure medication. You will get a lab measure for safety monitoring as recommended by the study pharmacist or physician, for example possibly during changes in your blood pressure medication. Phlebotomy, or other trained personnel, will draw 4 – 5 ml of blood at Vanderbilt General Clinic Research Center, or other suitable location. Pharmacists will be available every week at first at the barbershop and then less often (monthly) after your blood pressure goal has been reached. With your permission, the pharmacists will send progress notes to your usual physician after each visit to include in your medical record.

Your part of the study will last for a total of 6 – months to complete all of the activities of this study. You will answer surveys about yourself, your healthcare team, your health status, how you take your medication and your experience with your care. These will take about 30-45 minutes and will take place at the start of the study and at 6 – months. There will also be a brief telephone survey at 3 months that will take approximately 10 minutes. If you visit the emergency room or hospital during the study, you may be asked to provide permission to obtain records from that visit for the study team to review.

Description of the discomforts, inconveniences, and/or risk that can be reasonably expected as a result of participation in this study:
There is minimal risk associated with this study. Anxiety is a rare and typically not serious potential risk associated with high blood pressure caused by learning that one's blood pressure is elevated. Professional interviewers will be trained in study procedures which will include appropriate interaction with people like you who join the study. Uncontrolled high blood pressure is associated with increased risk of known high blood pressure complications including heart attacks, stroke, heart

failure, and chronic kidney disease. These risks are not due to study procedures but are risks due to the condition of uncontrolled high blood pressure.

Cost to you if you take part in this study.
If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Unforeseeable risks:
There may be a risk for a loss of privacy of the information you provide during the study. For example, we do not have control of who may hear or see certain information such as your blood pressure readings while you are in the barbershop. We will take every precaution that your information is stored only in the locations explicitly described on this consent form, and your information will be maintained indefinitely or destroyed at the time determined that all analyses and objectives have been accomplished

Compensation in case of study-related injury:
If it is determined by Vanderbilt and the investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury. There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study. If this study model proves to be effective in helping people control their high blood pressure, it may be repeated in other parts of the country offering an opportunity to improve health among black men. This may also provide a new way to introduce black men to future research opportunities.
b) The benefit you might get from being in this study: Being part of this research study will provide you with direct access to a clinical pharmacist to help you with better management of your high blood pressure.

Study Results:
Overall study results will be reported to Clinicaltrial.gov, and shared in research journals or meetings.

Alternative treatments available:
The alternative treatment is the option to not participant in this study.

Compensation for participation:
You were offered $25 after your second screening visit. You will also be offered $25 for each visit completed with the clinical pharmacist (up to 6 visits), $15 for completion of the telephone 3-month visit, and $100 at the completion of the final 6-month visit. You will also be offered a monthly $25 haircut voucher that you can use at the study barbershop. These payments will be made through a Subject Participant Debit Card program or pre-paid gift cards. You may receive up to $440 for taking part in this study. This amount may be taxable and will be reported to the Internal Revenue Service (IRS). We may ask you for your Social Security number and address before you are compensated for taking part in this study.

Circumstances under which the Principal Investigator may withdraw you from study participation:
The study is directed by Dr. David Harrison, and he may remove you from the study at any time, and you may request to be removed from the study at any time.

What happens if you choose to withdraw from study participation?

There will be no penalties or charges for payments you have already received if you withdraw early from the study, but you will not receive any more study payments after you leave the study.

Contact Information:

If you should have any questions about this research study or possibly injury, please feel free to contact study Principle Investigator, **David Harrison, MD at [redacted], co-investigator, [redacted], or Clinical Pharmacist, [redacted].**

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the **Institutional Review Board Office at (615) 322-2918 or toll free (866) 224-8273.**

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. A Data Coordinating Center and Data Entry Overview at the University of California in Los Angeles (UCLA) will be used for this study. The survey interviewers and the pharmacists will collect and transmit your information from the study electronically via a secure internet connection to a server operated by Westat, where any information that is directly identifiable to you individually (such as your name) is removed before the rest of your information without your identifiers (such as your blood pressure information) is sent to the UCLA CTSI Data Coordinating Center.

This study may have some funding support from the National Institute of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out information even if requested using legal means in a court.

Any disclosures or sharing of your study information that you agree to in this document are not protected under a Certificate of Confidentiality. This includes any study information added in your medical record or sharing your study information in future research. There are other privacy laws that govern medical records and future research, but any Certificate of Confidentiality would only apply to this study. Also, any disclosures or sharing of your study information that you make yourself are also not protected under a Certificate a Confidentiality.

Privacy:

Information collected about you in the study by the barbers and the pharmacists or research staff on the study forms are programmed into the blood pressure machines and sent to the Westat servers and later sent via a secure web-based system to the UCLA Data Coordinating Center. We will keep copies of your study pharmacist's progress note, copies of adverse event forms (if any occur), copies of your surveys conducted by study interviewers; copies of this informed consent document which includes your permission and authorization for release of your medical records; medical records sent by your primary care physician, blood pressure measurements from the barbershop; and the study pharmacists' collaborative practice agreements in your research chart which will be stored in a locked cabinet only accessible to the research staff. Paper copies of this informed consent document and any paper copy and survey material (identified by study ID number only) will be stored in a secured and locked cabinet at Vanderbilt University Medical Center.

The following people will have access to your individual private information that is identifiable to you.: **Vanderbilt approved key study personnel including principal investigator, co-investigator, study interviewers and data managers** will have access to the information collected on the study forms at screening, baseline, 3-month and 6-month assessment visits. The study pharmacist will have access to the information collected by the study interviewers, information provided by your own physician, the blood pressure measurements sent by the barber in the study, and information you give them yourself directly. Your own physician will have access to the information collected about you by the barber and by the pharmacist in the study.

The Data Coordinating Center at the UCLA Department of Biomathematics will distribute a copy of your study information that has been encrypted and de-identified on a secure web-based platform to the collaborating researchers at: **Cedars-Sinai, UCLA, and Vanderbilt University Medical Center.**

Authorization to Use/Disclose Protected Health Information:

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSONS AGREEING TO PARTICIPATE IN THIS STUDY:

I have read this informed consent document and the material contained in it has been explained to me verbally. All of my questions have been answered, and I freely and voluntarily choose to participate.

_____ _____
Signature of patient/ volunteer Date

Consent obtained by:

_____ _____
Signature Date

_____
Print Name and Title