July 2, 2018

Comparative Effectiveness of Health System vs. Multilevel Interventions to Reduce Hypertension Disparities (The RICH LIFE Project)

Patient Oral Consent Form

NCT02674464

PRINCIPAL INVESTIGATORS:
LISA A. COOPER, MD, MPH
JILL MARSTELLER, PHD, MPP

September 2015 – August 2022

ORAL CONSENT SCRIPT: PATIENTS

Protocol Title: Comparative Effectiveness of Health System vs. Multilevel Interventions to Reduce Hypertension Disparities

---

PURPOSE

You are being asked to take part in a research study called the RICH LIFE Project. This research is being done to help patients lower their blood pressure. This study will compare two ways to improve patients' health and experiences. One way is a standard clinic-based approach called the "standard of care plus" (SCP). Providers and staff in the SCP group will receive training and education about blood pressure measurement. Providers in the SCP group will also receive feedback on how well they are managing their patients' high blood pressure. The other way to improve patient health experiences uses a team to care for patients and is called "Collaborative Care/Stepped Care" (CC/Stepped Care). In the CC/Stepped Care group a care manager will work with patients to develop a care plan based on the patient's wants and needs. These patients may meet with a community health worker if needed. The patient's care team may also get help from medical specialists based on their care plan. Providers and staff in the CC/Stepped Care group will have the same blood pressure measurement education and training as those in the SCP group. Providers in the CC/Stepped Care group will also receive feedback on their performance, like the SCP group. Clinics will be assigned to SCP or CC/Stepped Care by chance (like the flip of a coin). You will receive the same approach to BP management as everyone else in your clinic who agrees to participate in the study.

Adult patients at participating clinics with high blood pressure plus one more risk factor for heart disease and stroke may be eligible to join this study.

How many people will be in this study?

About 1890 people will be in this study. There are 30 clinics taking part in this study. About 63 patients from each clinic will be in this study.

PROCEDURES

Your clinic has been assigned by chance (like the flip of a coin) to one of two study groups.
If you are a patient at a clinic assigned to the CC/Stepped Care group we will ask you to do the following:

- You will keep seeing your usual doctor.
- You will meet with a nurse care manager about your blood pressure and other health concerns for about one hour. The nurse care manager will work with you to develop an agreed upon care plan. Your care plan will be specific to your needs.
- You will meet with a community health worker who will give you a blood pressure machine to keep at home. The community health worker will show you how to take and record your blood pressure. This meeting will take place at the clinic.
- Depending on your care plan, you may meet with additional members of a "care team." These meetings will be scheduled for another date and time that works well for you. Care team members may include a dietitian, social worker, medication management specialist (who is either a nurse or pharmacist), health coach or education specialist, and a community health worker.
- Your care plan may include a community health worker. The community health worker may ask to visit you in your home. You may decline to have the community health worker visit you at home. If you decline, it will not affect your care or participation in this study.

- If your care plan includes a community health worker, the community health worker may ask to audio record (sound) up to 2 visits with you. You may refuse to be audio recorded. If you refuse, it will not affect your care or participation in this study.
- We will ask you to answer questions over the telephone about you and your health. We will ask you to answer questions today. We will also ask you to answer questions at 1 year after you start the study and again at 2 years. These yearly telephone calls will take about one hour. You will receive $25 each time you complete the telephone questions.
- We will also call you one time between the yearly calls to ask a few questions about any visits to emergency rooms, hospital admissions, or any serious problems with your health within the previous six months. These calls between the yearly calls will only last five to ten minutes. You will receive $10 each time you complete these calls.
- We are asking for your permission to look at your medical record and collect information about you and your health. This information may include your blood pressure, your height and weight, your medications, and your medical illnesses.
- We are asking for your permission to contact you after you complete your first survey. We may contact you to learn more about your life experiences and how you manage your health through an in-person interview. If you agree to do this, we will ask for your permission to audio (sound) record your answers at the interview. You will receive $60 for participating in this interview.
- We are asking for your permission to contact you after you complete your last survey. We may contact you to ask more in depth questions about your experience in the research study.
- We are asking for your permission to obtain information about you from the insurance claims related to the health care you receive before and during the study. This information helps us to better understand what medical services you received and why you might have received the services. Knowing what medical services patients in this program receive helps us understand how well the program works.

What questions do you have so far? **Answer questions.**

If you are a patient at a clinic assigned to the SCP group we will ask you to do the following:

- You will keep seeing your usual doctor. You will have your usual treatment for your high blood pressure.
- We will ask you to answer questions over the telephone about you and your health. We will ask you to answer questions today. We will also ask you to answer questions every year until the study ends in August 2020. These yearly telephone calls will take about one hour. You will receive $25 each time you complete the telephone questions.
- We will also call you one time between the yearly calls to ask a few questions about any visits to emergency rooms, hospital admissions, or any serious problems with your health within the previous six months. These calls between the yearly calls will only last five to ten minutes. You will receive $10 each time you complete these calls.
- We are asking for your permission to look at your medical record and collect information about you and your health. This information may include your blood pressure, your height and weight, your medications, and your medical illnesses.
- We are asking for your permission to contact you after you complete your first survey. We may contact you to learn more about your life experiences and how you manage your health through an in-person interview. If you agree to do this, we will ask for your permission to audio (sound) record your answers at the interview. You will receive $60 for participating in this interview.
- We are asking for your permission to contact you after you complete your last survey. We may contact you to ask more in depth questions about your experience in the research study.
- We are asking for your permission to obtain information about you from the insurance claims related to the health care you receive before and during the study. This information helps us to better understand what medical services you received and why you might have received the services. Knowing what medical services patients in this program receive helps us understand how well the program works.

ALL patients will be in this study for up to 3 years.

RISKS/DISCOMFORTS

The risk of harm or discomfort from participating in this study is not expected to be more than for the routine treatment of your high blood pressure.

The risks associated with participating in this study include the stress involved in answering questions about physical and emotional status. We hope you will answer all of the questions; however, you do not have to answer any question that you do not want to answer. You do not have to answer a question you find embarrassing or intrusive. You may also get tired or bored when we are asking you questions or when you are completing questionnaires.

If you agree to be tape recorded, there may be loss of confidentiality. You have the right to turn off the tape recorder at any time during the visit, to listen to the tape recording of the visit, and to remove your tape from the study if you change your mind. Tape recordings made during the course of the study will be safeguarded and their use will be limited to research purposes. All identifiers on the tape will be by code only. The code key will be destroyed at the end of the study.

There is a small risk that some information about you from an interview or insurance claim may become known to people outside this study. To the greatest extent allowed under the law, we will follow strict rules to protect the privacy of all the information we receive. Your name will not appear on any study form. Instead, we will label your forms with a code number. The link between your name and your code number will be kept strictly confidential. The information collected from your interviews and your insurance claims will be stored in computers that only authorized members of our staff can use. When we report the results of the study, we will combine the information about you with similar information about hundreds of other people, so your individual information will not be identifiable. After the study is completed, the data will be destroyed."

In case of home visit(s) by the study staff, including the Community Health Worker, Maryland law requires us to tell the local or state authorities if we suspect abuse or neglect of a child or dependent adult. Should a member of the study team encounter evidence of child, adolescent, dependent adult, or elder abuse or neglect, he or she will immediately stop the visit and inform the interviewee that he or she is required to report the matter to the study's Principal Investigator. Upon receipt of this notification, the PI will report suspected cases of child or adolescent abuse/neglect to the local department of child protective services or adult protective services. If you tell us that you plan to harm someone, we are required to contact the police. We may also warn the person who is at risk.

BENEFITS

There may be no direct benefit to you from being in this study. Some patients will receive a home blood pressure machine. Some patients will receive a pillbox. You may also benefit by learning about how to take better care of your blood pressure and other health concerns. If you take part in this study, you may help others in the future.

COST

There is no cost to participate in this study.

PAYMENT

As previously described, you will receive $25 each time you complete the telephone questions. You will receive $10 for completing the calls about any health events. Depending on your participation you may receive up to $95 for being a part of this study.

If we contact you to learn more about your life experiences and how you manage your health through an in-person interview, you will receive an additional $60 if you agree and complete the interview.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

VOLUNTARY PARTICIPATION

You do not have to agree to be in this study. If you do not want to join the study, it will not affect your care at Johns Hopkins or at your doctor's office.

You may refuse to answer any question(s) you do not wish to answer today or during follow up telephone calls.

If you have any questions about your rights as a research participant, or if you think you have not been treated fairly, you may call the Johns Hopkins Institutional Review Board (IRB) at 410-955-3008.

HIPAA DISCLOSURE

We will collect information about you in this study.

People at Johns Hopkins who are involved in the study or who need to make sure the study is being done correctly will see the information.

People at Johns Hopkins may need to send your information to people outside of Johns Hopkins (for example, government groups like the Food and Drug Administration) who are involved in the study or who need to make sure it is being done correctly. If the study has a sponsor, people at Johns Hopkins will send your information to that sponsor.

These people will use your information for the purpose of the study.

We will continue to collect information about you until the end of the study unless you tell us that you have changed your mind. If you change your mind and don't want your information used for the study anymore, you can call The Johns Hopkins Institutional Review Board at 410-955-3008. Just remember, if we have already used your information for the study, the use of that information cannot be cancelled.

We try to make sure that everyone who needs to see your information uses it only for the study and keeps it confidential - but, we cannot guarantee this.

A description of this clinical trial will be available on 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 with the clinical trials.gov identifier: NCT02674464.

Do you have any questions?

OBTAIN ORAL CONSENT

Do you think you would like to take part in this research? If you are interested in participating in this study, I will need your verbal consent.

Do you agree to participate in the study?

Yes _____No _____

Interviewer Signature _____

Date (MM/DD/YY) _____