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Wake Forest®
School of Medicine

Department of Adult Cardiology

TELEMEDICINE MANAGEMENT OF HYPERTENSION: A PRE-IMPLEMENTATION STUDY

Informed Consent Form to Participate in Research
Yashashwi Pokharel, MD, Principal Investigator

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 you have a diagnosis of high blood pressure. 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?

Approximately 116 million Americans have high blood pressure, but only 24% have their blood pressure controlled. There is an urgent need for better ways to manage high blood pressure. Multiple studies have previously shown that a telemedicine intervention to treat high blood pressure using home blood pressure values is more effective in controlling blood pressure than the current clinic-based treatment model. Nevertheless, use of telemedicine is not a routine practice partly because we don't understand yet whether this intervention is acceptable and suitable for patients. The purpose of this pilot study is to understand what makes it easier or difficult for patients to use the telemedicine intervention and also to understand whether the intervention is acceptable, good match and easy to use. Only then such intervention is more likely to be used by patients.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

In this study, we will pilot the telemedicine intervention in 20 adult patients 18 years or older with high blood pressure from two clinics, University Internal Medicine – Country Club Winston-Salem and Myers Park Internal Medicine Charlotte. Both men and women can participate with approximately ten people from each clinic, of which at least half will be African Americans.

WHAT IS INVOLVED IN THE STUDY?

The study team will review your medical history to select patients with the presence of the (1) diagnosis of high blood pressure; (3) systolic blood pressure >140 mmHg on last two clinic visits; (4) on stable blood pressure medications in the preceding six weeks; (4) possess a smart phone. Presence of a smart phone allows communicating home blood pressure values using a

secure application. The informed consent will be obtained via telephone or in person by the study team.

If you agree to participate in the study, you will engage in the following:

- Participation in the telemedicine intervention for three months and is described in next section.
- A telephone or video interview and online surveys after the telemedicine intervention ends to understand how easier or difficult was it for you to use the intervention and was it acceptable, a good match and easy for you to use. This interview can last approximately 30 minutes and will be audio recorded. Understanding the part of the intervention that you considered was helpful and was feasible for you and matched your need will help the study staff further modify the telemedicine intervention so that patients with high blood pressure similar to you are more likely to use the intervention in the future.

If you take part in this study, you will participate in the study interventions that consists of home blood pressure monitoring, telemedicine-based hypertension coaching, and medication recommendations as detailed below.

Home blood pressure monitoring: As part of the intervention, you will be asked to monitor blood pressure at home once daily using standardized methods. Blood pressure data will be automatically sent to a secure application, Carium Inc, from your smart phone after you measure blood pressure and tap a button. Study staff will be able to access your blood pressure data using investigator's Carium portal. The study staff will provide you a blood pressure monitor, purchase a subscription for the Carium application, and help set up and connect the Carium application in your phone with the blood pressure monitor. At the beginning of the study, study staff will train you how to use the blood pressure monitor and set up the Carium application which will require your email address. We will also email you a link showing standardized methods to measure home blood pressure. In addition, study staff will help you if you encounter any problem using the blood pressure monitor during the study intervention. For example, if you send three or less blood pressure measurements in a week, then study staff will contact you (initially using Carium portal followed by calling, if no response) to assess for any technical issues.

Telemedicine-based hypertension coaching: Trained nurses will speak with you for approximately 30 minutes for 3 coaching sessions to help you better take care of high blood pressure. They will discuss what high blood pressure is, strategies to regularly take blood pressure medications, understand medications' potential side effects, improve skills in healthy eating, physical activity, weight management, tobacco and alcohol use, and assess for sleep apnea. In addition, the nurse will call you five more times up to ten minutes each time every 2-3 weeks to follow up on items you have discussed and to check if you have any difficulty or need help. Nurses will also assess the accuracy of home blood pressure measurement technique during these calls. Depending on your need, the frequency and duration of contact between you and the nurses can be changed.

Medication recommendations: In collaboration with your primary care doctor, your blood

pressure will be treated with appropriate medications, similar to what your doctor would otherwise do. Study staff will contact you for any blood pressure medication changes. Medication changes will be triggered if ≥25% of your home blood pressures do not meet the target systolic blood pressure goal of <130 mmHg in the preceding six weeks. We will also consider diastolic blood pressure in management (goal <80 mmHg), but the focus will be systolic blood pressure. If a medication change occurs (i.e., either dose change or a new medication started), we will wait for at least six weeks before another medication change. This means that over three months of intervention, you can have up to two medication changes.

Additional support: We will ask you if you need any additional support from a community health worker or a social worker. With your permission, community health worker can visit your home for additional help. Community health worker or a social worker can provide assistance under the scope of their practice within each clinic and could include technology assistance (help with blood pressure monitor or Carium app use, setting up email), education (about hypertension, medication adherence, lifestyle counseling), networking with clinic (help with medication refill), or support related to social issues that can affect your health (food, commute).

How Long Will I Be in the Study?

You will be in the study for about 9 months. The telemedicine intervention will be for 3 months. We expect the interviews and online surveys to last no more than another 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 what would occur for treatment of blood pressure by your primary care physician based on prior studies. These include side effects of the same medications that your primary care physician would otherwise prescribe, and effects of low blood pressure like dizziness or passing out. 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. As part of this study, you will be asked questions about your blood pressure and your skills in its management and how best you may be able to use telemedicine approach to control blood pressure, including possible barriers. 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.

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 to your health.

Study staff will notify your primary care physician with any safety issues such as systolic blood

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pressure >180 mmHg, diastolic blood pressure >120 mmHg, systolic blood pressure <100 mmHg, passing out or other events such as hospitalizations, emergency department or urgent care visits, or deaths. Due to close supervision and the nature of the study, we do not expect any of these events as an adverse effect of the study intervention, which is otherwise no different than usual standards of practice. Although dizziness or passing out could theoretically occur, the likelihood of this happening as an effect of the intervention is negligible because the intensity of the medication changes is modest.

You may be asked to call 911 or go to emergency department if you develop life threatening conditions related to your blood pressure like stroke, heart attack, acute heart failure or passing out.

If a participant is observed to be in threatening health (regardless of whether it is related to the study or not) or describes an adverse event, his or her primary care provider and the principal investigator will be notified. Dr. Pokharel will provide oversight for the data management team to identify any possible concerns in the surveillance for adverse events. All unanticipated problems and safety concerns will be reported to the IRB at AHWFB per institutional policy. A plan for regular ascertainment of adverse events will include scheduled calls by nurses to patients throughout the study period.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be:

To appreciate barriers and facilitators in the delivery of telemedicine intervention for blood pressure management.

To help understand best strategies to use the telemedicine intervention for blood pressure management so that the intervention is acceptable and appropriate for patients.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. Your participation is entirely voluntary. If you do not participate, the care that you receive at Atrium Wake Forest Baptist Health will not be affected. You should talk to your doctor about all the choices you have for any interventions pertaining to your high blood pressure.

WHAT ARE THE COSTS?

Study staff will provide you a blood pressure monitor and pay for a subscription for the Carium application. Costs for your regular medical care, including medications for blood pressure

treatment, will be the patient's responsibility. The investigators are not testing any unapproved medications.

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.

I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by Carium application or the email I provided to send information, reminders, and to communicate with me about the research study. I accept the risk that individuals not involved in the research study may be able to access the messages. I also understand that messaging via Carium application or email is not to be used for emergency situations.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $*50* at the end of the study after the final interview and surveys are administered, if you complete all the scheduled study visits.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Atrium Wake Forest Department of Cardiology. 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 HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

If you are injured, the sponsor may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the sponsor is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent research insurance

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coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information, which means that this information can identify you such as your name and date of birth. Additional information we will collect for this research study includes**:**

- Your education
- Household income
- Employment
- Comfort with using technology like a smart phone
- Adequacy of medical insurance
- Your confidence in filling medical forms
- Blood pressure values
- Patient related outcomes
- Surveys
- Barriers/Facilitators
- Your opinions about the program, satisfaction, healthcare

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

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.

Study staff will chart your average blood pressure, the numbers of contacts they had with you, contact duration, technical issues, medication changes, adverse effects, and safety issues. This data will be reviewed, and clinically relevant summary results will be made available to nurses every week. The nurses will document the clinical summary in the electronic medical record.

As part of this research study, your interview will be recorded. The recording will be transcribed, and only data that does not identify you will be considered for analysis. Similarly, the data from the survey response that does not identify you will be considered for analysis.

Recordings will be considered Protected Health Information if they contain information that identifies you. You understand that you may request the photographing, filming, taping or recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the recording before it is used, but doing so may affect your eligibility to remain in the research study. You should also understand that you will not be able to inspect, review, or approve the recordings or other media (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the recording used in this research study:

_____ I would like the recordings of me to be destroyed once their use in this study is finished. I understand that destroying the recordings at the end of this study will not affect any prior use of the photographs/videotapes/audiotapes/recordings.

____ The recordings of me can be kept for use in future studies provided they are kept secure, and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use. 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.

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Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

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.

AND/OR Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. 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 Dr. Yashashwi Pokharel 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:

Yashashwi Pokharel
[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

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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.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this study.

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.

You will be given any new information if we become aware that the information 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, Dr. Yashashwi Pokharel [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

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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

Legally Authorized Representative Name (Print)_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject_____

Legal Representative Signature: _____ Date:_____
Time:_____ am pm

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