Informed Consent

Department of Neurology

Telehealth-Enhanced Assessment and Management after Stroke-Blood Pressure (TEAMS-BP)
Informed Consent Form to Participate in Research
Cheryl Bushnell, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this study is to determine the best strategy to help individuals improve blood pressure control after a stroke. The study will test two different interventions. Both are based on treatments that have been shown to successfully lower high blood pressure. They will both include individualized care planning, blood pressure management recommendations, and referrals to needed community resources. The two interventions are:

1) Intensive Clinic Management, which consists of clinic visits, you will complete at home blood pressure monitoring, and health education.
2) Intensive Tailored Telehealth Management, which consists of telehealth (video or phone) visits, health coaching, and remote blood pressure monitoring.

You are invited to be in this study because you have recently experienced a stroke. You will need to have access to a smartphone or tablet with internet access to take part in this study. You will have to install applications (apps) on your smartphone or tablet with the help of the study coordinator. These apps will allow you to receive health education and coaching, and monitor your blood pressure and physical activity.

Participation in this study will last up to 16 weeks and will involve:

- Attending 2 study visits to measure your blood pressure and collect information via questionnaires
- Monthly check-in phone calls
- Participating in a 3-month intervention that includes 2 or 3 in-person OR telehealth visits, regular blood pressure monitoring, weekly health education OR coaching, wearing a device to measure physical activity, completing daily logs, and questionnaires.

All research studies involve some risks. A risk to this study that you should be aware of is your blood pressure becoming too low. It may drop low enough to cause symptoms such as lightheadedness after standing up or with exercise, or make you feel tired. You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. This is not a treatment study so the only other option is not to participate. 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 Dr. Cheryl Bushnell 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 scientists learn new information that may help other people in the future. You are being asked to be in this study because you have had a stroke. 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?

An important question for stroke patients and caregivers is how to prevent another stroke. We will be assisting patients who have had a stroke to control and lower blood pressure (BP) and to put into action healthy lifestyles to help lower BP. This is important for reducing the risk of recurrent stroke. However, it can often be difficult for health care systems to implement new models (ways) of healthcare practice to meet these needs. The TEAMS-BP study will compare two (2) interventions to help patients who have had a stroke control their BP: 1) an Intensive Clinic Management model (also called ICM), that includes clinic visits and health education versus 2) an Intensive Tailored Telehealth Management model (also called ITTM) that includes individualized care planning, health coaching, and referrals to needed community resources.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

100 people at 2 research sites will take part in this study, including approximately 50 people at this research site. In order to identify the 100 participants needed, we may need to screen as many as 150 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the two study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal (1 out of 2) chance of being in either group.

Study Group 1: an Intensive Clinic Management model (also called ICM); or

Study Group 2: an Intensive Tailored Telehealth Management model (also called ITTM)

If you take part in this study, you will have to take part in the following activities:

Study Events	Description	Approximate Time Required	Activities During Event
Baseline in-person visit	You will take part in brief questionnaires to establish whether or not you are eligible to participate. If you are eligible, you will complete a series of questionnaires. You will be randomly assigned (like flipping a coin) to a study intervention at this visit.	3 hours	• Questionnaires* • Assignment to first treatment • Individualized care planning • Receipt of referrals to community resources and prescriptions for blood pressure medications • Scheduling future visits
Study Intervention	You will receive a study intervention for up to 12 weeks.	The time required will depend on the intervention you are assigned	• Activities will depend on the intervention. • Each intervention is described below
Follow-up in-person visit at 3 months	You will participate in this activity to collect final study information about how the treatment worked for you and your experience as a participant so that we can learn how to improve the study for future participants.	1 hours and 30 minutes	• Questionnaires* • Measurement of blood pressure
Check-in Phone Calls	Study staff will call you each month to check in and see how you are doing.	10 minutes	• Questionnaires*
Follow-up Texts and/or Emails	You will receive texts or emails from the study staff. This will include reminders of upcoming visits.	<5 minutes	• Notifications

* Some questionnaires will be available to complete online prior to the visit, and others will be completed in-person, but all can be completed in-person.

Study Interventions

You will be assigned to one of the following interventions during your participation in this study. Neither you nor the study investigator will choose the treatment. You will be assigned to study interventions by chance (like flipping a coin). Please see below for more details about each treatment.

Intensive Clinic Management (ICM) involves the following activities:

- Attending an in-person clinic visit every 1 to 2 months. At these visits, a provider will help you manage your blood pressure. For example, they may prescribe medications or make changes to your current medications.
- Receiving weekly health coaching text messages. These messages will remind you about the importance of taking your medicines, eating a healthy diet, and safely engaging in exercise.
- Self-monitoring your blood pressure at home. You will be asked to record your blood pressure numbers on a daily log. You will receive a blood pressure monitor and log provided as part of the study at no cost.

Intensive Tailored Telehealth Management (ITTM) involves the following activities:

- Attending telehealth (video or phone) visits every month. At these visits, a provider will help you manage your blood pressure. For example, they may prescribe medications or make changes to your current medications.
- Taking part in health coaching phone or video calls. A health coach will work with you to help you make healthy changes to your diet, exercise and other habits.
- Self-monitoring your blood pressure and physical activity. You will receive a blood pressure monitor and Fitbit provided by the study at no cost. You will be asked to transmit data from these devices to your smartphone or tablet. The Fitbit and blood pressure monitor will be yours to keep at the end of the study. If you lose these devices before the end of the study they will not be replaced and this will end your participation.

As part of your participation in the study, we will send copies of your blood pressure results to your primary care provider.

If you do not qualify for randomization or decide that you no longer wish to participate in the study, we will not collect any further data from you or your medical record. Data collected from the time of consent will be shared with our Data Coordinating Center at the University of North Carolina at Chapel Hill.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 16 weeks.

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. This is not a treatment study so

there should be no serious consequences if you stop participation early.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the interventions we are studying include:

Risk Associated with Assessments

Questionnaires: as part of this study you will be asked questions about your physical health, diet, mental health, and substance use. Some participants may feel minor discomfort sharing these topics.

Blood Pressure Measurement: When blood pressure is taken, the blood pressure cuff may cause discomfort or bruising to the upper arm depending on the device you are given.

Risk Associated with Interventions

Blood Pressure Lowering: For some participants, blood pressure may drop low enough to cause symptoms such as lightheadedness after standing up or with physical activity, or you could feel tired.

Medications: Some of these side effects could include cough, electrolyte imbalance (when your body has too much water or not enough), and renal dysfunction which is a condition where the kidneys stop working and are not able to remove waste and extra water for the blood and keep body chemicals in balance.

New technologies: Some participants may feel a minor discomfort or stress with new or unfamiliar technology including smartphone apps, Fitbits, and video visits. Additionally, some participants may experience stress from daily text messages or app notifications while participating in the study.

Risk Associated with Confidential Information: Despite significant protections put in place to keep your personal information safe, breaches of confidentiality, while unlikely, are possible. Your data will be handled in the highest of standards using security systems put into place with all applications used in this study.

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. Pregnant women are excluded from participation in this study.

An Independent Medical Monitor will be reviewing the data from this research throughout the study to identify possible safety issues to participants and to provide advice and recommendations on possible changes to the research study for the protection of participants.

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 better controlled blood pressure, gaining a better understanding about recovery after having a stroke, and understanding the importance of maintaining the combination of medication and healthy habits such as monitoring blood pressure, physical activity, and a healthy diet to reduce your risk of having another stroke.

Because individuals respond differently to these interventions, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

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

WHAT ARE THE COSTS?

Blood pressure monitors and Fitbits that are 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.

Before you take part in this study, you should call your health insurer to find out if the cost of remote patient monitoring and chronic care management will be paid for by the plan. Some health insurers may not pay for these costs. You will have to pay for any costs not covered by your health insurer. The cost would be the professional and technical fees billed by your provider.

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.

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 text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency

situations.

WILL YOU BE PAID FOR PARTICIPATING?

You will be given a $200 gift card at your final study visit. If you withdraw for any reason before the final study visit you will not receive a gift card.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

TEAMS-BP is sponsored by the Patient Centered Outcomes Research Institute (PCORI). The sponsor is providing money or other support to the researchers to help conduct this study. Drs. Cheryl Bushnell, Pamela Duncan, and Umit Topaloglu are co-inventors of a digital health assessment and clinical management tool being utilized in the study. Dr. Bushnell, Dr. Duncan, Dr. Umit Topaloglu, and Wake Forest University Health Sciences (WFUHS) own equity in Care Directions, Inc., the company which licenses the assessment and management tool. This means that WFUHS and the inventors may financially benefit from the research results and future sales of the assessment tool.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

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 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.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call *Dr. Cheryl Bushnell* at [redacted] *(24 hour number*).

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you, from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes, but is not limited to such things as

your name, address, telephone number, and date of birth.

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 will 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 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.

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 an indeterminate period of time. This authorization does not expire.

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. Cheryl Bushnell 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:

Cheryl Bushnell, MD, MHS
Atrium Health Wake Forest Baptist
[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.

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. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. 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.

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, *Dr. Cheryl Bushnell* at [redacted] *(24 hour number*).

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 Signature:_____ 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