Stroke Telemedicine Outpatient Program (STOP) for Blood Pressure Reduction

NCT03923790

Version Date: 11/10/2020

INFORMED CONSENT FORM TO TAKE PART IN RESEARCH

Simple Study Title: **STOP Stroke Study**

Full Study Title: **Stroke Telemedicine Outpatient Prevention Study**

Principal Investigator: Anjail Sharrief MD MPH, Assistant Professor of Neurology, McGovern Medical School

Study Contact: Gabretta Cooksey, Research Coordinator, 713-500-7153

The purpose of this study is to determine if the STOP Program:

1. Leads to decreased blood pressure.
2. Provides a faster, more convenient method of receiving care.
3. Reduces future stoke risk.
4. Improves collaboration of Health Care Professionals
5. Improves access to stroke follow-up care

If you choose to participate in this study, you will be followed by our clinicians one of two ways.

1) You will be asked to log into a device to collaborate with our clinician's regarding your blood pressure. We will determine if there is a need to change medication or if an in person visit will be needed.

2) You will be offered a hospital follow up visit in our clinic.

The total amount of time you will be in this study is 6 months. There are potential risks involved with this study that are described in this document. The risks include adverse effects associated with aggressive blood pressure reduction. We have chosen a conservative and currently AHA recommended BP goal and will monitor for hypotension, syncope, and falls that may result from hypotension.

If you are interested in participating, please continue to read below.

You are invited to take part in this research study. Your decision to take part is voluntary. You may refuse to take part or choose to stop from taking part, at any time. A decision not to take part or to stop being a part of the research project will not change the services available to you from your doctor or UTHealth or Memorial Hermann Hospital.

What is the purpose of this research study?

The purpose of this research study is to evaluate the effectiveness of the Stroke Telemedicine Outpatient Program (STOP) at reducing blood pressure after stroke in patients who are at risk for blood pressure.

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Who is being asked to take part in this study?

You have been invited to join this research study because you have recently had a stroke. This study plans to enroll a total of 100 people at Memorial Hermann Hospital. The overall study will last 30 months.

What will happen if I take part in this study?

If you agree to take part in this study you will be randomized (similar to flipping a coin) to receive usual care (referral to a clinic neurologist and your primary care physician) after your initial stroke clinic visit or care in the STOP program for post-stroke risk factor and assessment management. It is not known whether care provided by the STOP program will be of benefit compared to usual care. For this reason, some study participants will receive usual care. This will allow a careful comparison with usual care to study the effectiveness of a comprehensive approach to post-stroke blood pressure reduction via telemedicine. There is a 50% chance you will receive care from the STOP study and a 50% chance that you will receive usual care. The study procedures are listed below:

If you are randomized to the STOP-Stroke group:

- At the time of discharge, you will receive a package containing an iPad with wireless access and a bluetooth enabled blood pressure monitor that allows automatic transmission of your blood pressure to a secure website to be viewed by the study team.
- Before hospital discharge, you will be instructed in use of the equipment. You will complete a questionnaire including a depression screen, a dietary assessment, a cognitive screen, and a sleep apnea screen.
- You will receive a phone call at 72 hours by the discharge nurse navigator or social worker to assure that you have received your medications and follow-up appointments.
- The first video visit will occur 7 days after discharge. A stroke prevention-trained nurse practitioner or stroke physician, social worker and pharmacist will attend this video visit.
- Additional video visits will occur 1 month, 3 months, and 5 months after enrollment.
- You will receive educational messaging via text once every other week throughout the study period.
- You will have an in-person visit 6 months after enrollment and will return any UTHealth equipment given to you. IPAD, MiFi, Bluetooth enabled blood pressure monitor, 24-hour ambulatory blood pressure monitor. This will take one hour of your time. You will be compensated upon completion of this visit ($50).
- You will be contacted by the research coordinator by phone at 1 month, 3 months, 5 months and 6 months after discharge for additional assessments. These will each take 10-20 minutes of your time.

If you are randomized to usual care:

- You will complete questionnaires including a depression screen, a dietary assessment, a cognitive screen, and a sleep apnea screen prior to discharge.
- You will be contacted by the discharge nurse navigator or social worker at 72 hours to determine if you have received your medication and made your appointments.

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- You will be offered a standard of care hospital follow up visit in person or by telemedicine with a stroke prevention-trained nurse practitioner or stroke physician within 2 weeks of hospital discharge.
- Follow-up with your primary care provider to monitor your blood pressure.
- You will have an in-person visit 6 months after enrollment and will return any UTHealth equipment given to you. 24-hour ambulatory blood pressure monitor. This will take one hour of your time. You will be compensated upon completion of this visit ($50).
- You will be contacted by the research coordinator by phone at 1 month, 3 months, 5 months and 6 months after discharge for additional assessments. These will each take 10-20 minutes of your time.

How long will you be in the study?

You will be in this study for up to 6 months.

What choices do you have other than this study?

If you do not wish to participate in this study, you will be offered a clinic visit in our stroke clinic and will follow-up with your primary doctor.

What are the risks of taking part in this study?

Possible side effects depend on prescribed medication, which may vary from paient to patient. All treatments are usual care and you would have similar risks even if you were not enrolled in this study. Since this study involves collecting your private health information, there is a possible risk of breach of confidentiality.

You may get tired when we are asking you questions or you are completing questionnaires. You do not have to answer any questions you do not want to answer.

What are the benefits to taking part in this study?

All participants will receive educational materials about the importance of blood pressure reduction after stroke. All enrolled subjects will receive 24-hour blood pressure monitoring at study end.

Can you stop taking part in this study?

You may decide to stop taking part in the study at any time. A decision not to take part or to stop being a part of the research project will not change the services available to you from UTHealth.

What happens if you are injured during the study?

If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, all needed facilities, emergency treatment and professional services will be available to you, just as they are to the community in general. You should report any injury to Dr. Anjail Sharrief 713-500-6538 and to the Committee for the Protection of Human Subjects at (713) 500-7943. You will not give up any of your legal rights by signing this consent form.

What are the costs of taking part in this study?

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If you decide to take part in this research study, you will not incur any additional costs. Any medications, studies, or procedures recommended through the program will be considered standard of care and will be billed to you or your insurance. You will be compensated $50.00 at the end of the 6-month visit.

How will privacy and confidentiality be protected?

Please understand that representatives of the University of Texas Health Science Center at Houston, and the sponsor of this research may review your research and/or medical records for the purposes of verifying research data, and will see personal identifiers. However, identifying information will not appear on records. The only exception is information that is shared with your primary care provider which may contain your name, date of birth, and treatment/service dates. You will not be personally identified in any reports or publications that may result from this study. There is a separate section in this consent form that you will be asked to sign which details the use and disclosure of your protected health information.

Whom can you contact if you have questions about the study?

If you have questions at any time about this research study, please feel free to contact Dr. Anjail Sharrief at 713-500-6538 as they will be glad to answer your questions. You can contact the study team to discuss problems, voice concerns, obtain information, and offer input in addition to asking questions about the research study.

AUTHORIZATION TO USE AND DISCLOSE

PROTECTED HEALTH INFORMATION FOR RESEARCH

Patient Name:_____Date of birth: _____

Protocol Number and Title: HSC-MS-18-0925 Stroke Telemedicine Outpatient Prevention Study
Principal Investigator: Anjail Sharrief-Ibrahim

If you sign this document, you give permission to The University of Texas Health Science Center at Houston AND/OR Memorial Hermann Healthcare System to use or disclose (release) your health information that identifies you for the research study named above.

If you sign this document, you give permission to the researchers to obtain health information from the following health care providers:

Name of Provider	Address of Provider	Fax Number of Provider

The health information that we may use or disclose (release) for this research includes all information in your medical record including results of physical examinations, medical history, lab test*s. Protected*

health information will be shared with your primary care physician including, name, date of birth and service and treatment dates.

The health information listed above may be used by and/or disclosed (released) to researchers and their staff. The researchers may disclose information to employees at The University of Texas Health Science Center at Houston AND/OR Memorial Hermann Healthcare System for the purposes of verifying research records.

The University of Texas Health Science Center at Houston AND/OR Memorial Hermann Healthcare System is required by law to protect your health information. By signing this document, you authorize The University of Texas Health Science Center at Houston AND/OR Memorial Hermann Healthcare System to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your child's information with others without your permission, if permitted by laws governing them.

If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes. No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Please note that health information used and disclosed may include information relating to HIV infection; treatment for or history of drug or alcohol abuse; or mental or behavioral health or psychiatric care. In case of an adverse event related to or resulting from taking part in this study, you give permission to the researchers involved in this research to access test, treatment and outcome information related to the adverse event from the treating facility.

Please note that you do not have to sign this Authorization, but if you do not, your child may not participate in this research study. University of Texas Health Science Center AND/OR Memorial Hermann Healthcare System may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about your child as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to:

Dr. Anjail Sharrief-Ibrahim
The University of Texas Health Science Center at Houston
Address: 6431 Fannin, [redacted] Houston, TX 77030.
Phone: 713-500-6538
Fax: 713-500-0692

Privacy Officer
Memorial Hermann Healthcare System
909 Frostwood
Houston, Texas 77074
Fax: 713-338-4542

This Authorization will expire six years after the end of the study.

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SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part. Make sure that any questions have been answered and that you understand the study. If you have any questions or concerns about your rights as a research subject, call the Committee for the Protection of Human Subjects at (713) 500-7943. You may also call the Committee if you wish to discuss problems, concerns, and questions; obtain information about the research; and offer input about current or past participation in a research study. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

I give my consent to participate

Signature of Participant	Print Name	Date

Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date/Time

CPHS STATEMENT: This study (HSC-MS-18-0925) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at (713) 500-7943.