



INFORMED CONSENT FORM TO TAKE PART IN RESEARCH

Simple Study Title: VIRTUAL

Full Study Title: Video-based Intervention to Reduce Treatment and Outcome Disparities in Adults Living with Stroke or TIA

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

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

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 UTHealth Houston or Memorial Hermann Hospital.

The purpose of this study is to test whether the VIRTUAL telehealth intervention improves blood pressure control after stroke or transient ischemic attack. If you choose to take part, you will be randomized to receive care over telehealth with remote blood pressure monitoring or standard post-stroke care. You will be asked to check your blood pressure daily and also meet with your outpatient stroke provider at designated times either in person or through video visits. Since this study involves collecting your private health information, there is a possible risk of breach of confidentiality. We have procedures in place to minimize this risk. You may get tired when we are asking you questions or you are completing questionnaires. Benefits include a free blood pressure monitor and enhanced post-stroke blood pressure monitoring that is not typically provided to stroke patients. Participation is voluntary and the alternative is not to take part in the study.

What is the purpose of this research study?

The purpose of this research study is to evaluate the impact of the Telehealth Intervention at improving blood pressure control after stroke.

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 534 people. The overall study will last 5 years.

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 treatment through the VIRTUAL (telehealth) Intervention or through Standard Care. It is not known whether care provided by the Video-Based Intervention will be of benefit compared to Standard Care.

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There is a 50% chance you will receive care from the Video-Based Intervention and a 50% chance that you will receive Standard Care. The study procedures are listed below:

All enrolled patients will receive the following:

- Before hospital or rehabilitation discharge, you will receive a blood pressure monitor and will be instructed to check your blood pressure daily. You will also complete questionnaires that ask questions about different factors that impact your health.
- You will receive a phone call within 3 days of hospital discharge to assure that you have received your medications and follow-up appointments (5-minute call).
- You will receive phone calls at 3 and 9 months with questions about your health and clinical care (10-minute calls).
- At 6-months and 12-months you will have study outcome visits. In-person clinic visits will be offered at these time-points, but if you cannot attend a clinic visit, you will be offered an in-person home visit or telemedicine visit instead. You will be asked to wear a 24-hour ambulatory blood pressure monitor that you will return the following day. You will be compensated for the completion of these visits (\$50).

If you are randomized to the VIRTUAL (Telehealth) Intervention:

- At the time of hospital discharge, along with the blood pressure monitor, you may also receive an iPad with internet access if needed for the video visits.
- The first video visit will occur within 2 weeks (average 1 week) of hospital discharge. A stroke provider, social worker and pharmacist will conduct this visit.
- Additional video visits will occur 1 month, 3 months, and 5 months after hospital discharge.
- A pharmacist will check your blood pressure readings through a secure website (every two weeks) and adjust your blood pressure medications as needed (for 6 months).
- You will be asked to return the remote blood pressure monitor at 6 months, but will be given a new BP monitor to keep.

If you are randomized to Standard Care:

- You will see a stroke provider within 2 weeks of hospital discharge and 3 months after discharge.
- Additional visits will occur at the discretion of your doctor or nurse practitioner.
- A pharmacist will call you monthly to check your blood pressure readings and will communicate to your primary doctor the need to further adjust your medications.
- You will be asked to return the original monitor, but will be given a new BP monitor to keep..

How long will you be in the study?

You will be in this study for 12 months.

What choices do you have other than this study?

If you do not wish to participate, you will follow-up with our stroke clinic and with your primary doctor.

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 UTHealth
Houston

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What are the risks of taking part in this study?

Since this study involves collecting your private health information, there is low risk of breach of confidentiality. Electronic data is secured behind necessary firewalls and password protected. We use a code instead of your name for the transmission of data over the web-based portal. Finally, video-visits are conducted over a UTHHealth-approved encrypted platform.

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 a blood pressure monitor and pharmacy assistance for controlling blood pressure. You will be guaranteed care for the study duration whether or not you are insured. All enrolled subjects will receive 24-hour blood pressure monitoring one at 6-months and one at 12-months.

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 UTHHealth Houston.

What happens if you are injured during the study?

In the event of injury resulting from this research, UTHHealth Houston and/or Memorial Hermann Health System are not able to offer financial compensation nor to absorb the costs of medical treatment. 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 or your insurance company will be billed for any treatment. 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?

There are no costs to take part in this study. All medications provided and standard clinical visits recommended through the program will be considered standard of care and will be billed to you or your insurance. If you do not have insurance your visits will be covered by the study.

Will you be paid for taking part in this study?

You will be compensated \$50.00 at the 6 months clinic visit and 12 months clinic visit and \$50 at the return of ABPM machine with successful BP measurements total of \$100 per visit. If you live more than 25 miles from the medical center and return to the clinic for follow-up, you will receive \$100.00 upon completion of the 6-month and 12-month visits. If you receive a bill that you believe is related to your taking part in this research study and is not related to routine care, please contact Dr. Anjail Sharrief at 713-500-6538.

How will your privacy and confidentiality be protected?

Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

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If you sign this document, you give permission to UTHealth Houston and/or Memorial Hermann Health System to use and disclose (release) your health information. The health information that we may use or disclose for this research includes information related to your stroke and follow up care. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the private information (data) and biospecimens (samples) collected in this study. After we remove all identifiers, the data or samples may be used for future research or shared with other researchers without your additional informed consent.

If you are not comfortable with the use of your data for future research, you may not want to participate in this study.

People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them. You will not be personally identified in any reports or publications that may result from this study. 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.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records and medical records for the purposes of verifying study data:

- Representatives of UTHealth Houston and/or Memorial Hermann Health System
- Representatives of the sponsor of this research including contract research organizations
- Members of Data and Safety Monitoring Boards (an independent group of experts that reviews this study's data to make sure participants are safe and the research data is reliable)
- Companies engaged with UTHealth Houston for the commercialization of the results of the research study

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth Houston and/or Memorial Hermann Health 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 you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact Dr. Anjail Sharrief in writing at 6421 Fannin St MSB 7.110, Houston, TX 77030-1503.

This Authorization will expire 15 years after the end of the study.

Certificate of Confidentiality:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

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There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own 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. 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.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at (713) 500-7943.

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you

_____ Printed Name of Subject	_____ Signature of Subject	_____ Date
_____ Printed Name of Legally Authorized Representative	_____ Signature of Legally Authorized Representative	_____ Date
_____ Printed Name of Person Obtaining Informed Consent	_____ Signature of Person Obtaining Informed Consent	_____ Date

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