Official Title: Reducing Stroke Risk in African-American Men

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UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 12.2018)

Project Title: Reducing stroke risk in African-American men - TEAM2 (RCT)

Principal Investigator: Martha Sajatovic MD

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?
You are being asked to participate in a research study because you are an African-American man who has had a stroke or TIA (mini-stroke) within the past 10 years.

Things I should know about a research study
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Introduction/Purpose
The purpose of this research is to find out if a group educational and behavioral intervention, called **T**arget**E**d M**A**nage**M**ent Intervention (TEAM), helps African-American men with reducing their stroke risk factors. You will be one of 160 participants enrolled in this study at CWRU/UH.

Key Study Procedures
We expect that you will be in this research study for about 9 or 12 months, depending on when you join the study. During that time you will be asked to come in for 5 or 6 study assessment visits, 1 individual session, 5 group educational session visits (over 8 weeks), and 6 brief phone calls (spread over 12 weeks). More detailed information about the study procedures can be found under “Detailed Study Procedures”.

Key Risks
It is possible that some of the questions you are asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question. You may also feel tired after completing all the questionnaires or the educational sessions. More detailed information about the risks of this study can be found under “Detailed Risks”

Benefits
We cannot promise any benefits to you or others from your taking part in this research. However, you may find it helpful to participate in the educational sessions.

Alternatives to Study Participation
Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Detailed Study Procedures
As a participant in this study, you will be asked to come to the W.O. Walker Center and/or the Dahms Clinical Research Unit (DCRU) at UHCMC main campus. If you join the study prior to August 1, 2024, your participation in this study will last for about 12 months and will involve 6 study assessment visits, 1 individual session, 5 group educational session visits (over 8 weeks), and 6 brief phone calls (spread over 12 weeks). If you join the study on or after August 1, 2024, your participation in this study will last for about 9 months and will involve 5 study assessment visits, 1 individual session, 5 group educational session visits (over 8 weeks), and 6 brief phone calls (spread over 12 weeks).

If you are not able to come in for a visit at the W.O. Walker Center or the DCRU you may be able to complete some of your visits over the internet or by phone, at your own home by trained personnel or by doing some procedures yourself at home. Study staff will discuss with you the most appropriate way to obtain all of the study information from you.

If you agree to participate in this research, we would ask you to do the following things (you may refer to the Study Schedule of Events on the next page):

Screening
At this visit, the following screening procedures will be performed to determine if you can take part in this study:

- you will sign the informed consent form
- you will be asked basic demographic questions about facts such as your age and gender

The screening visit will last about 60 minutes or 1 hour.

If you are not able to come in to the office for an in-person visit, your blood pressure may be taken at your home by trained personnel, or you may be given a home blood pressure

monitor so you can take your blood pressure at home yourself throughout the study.

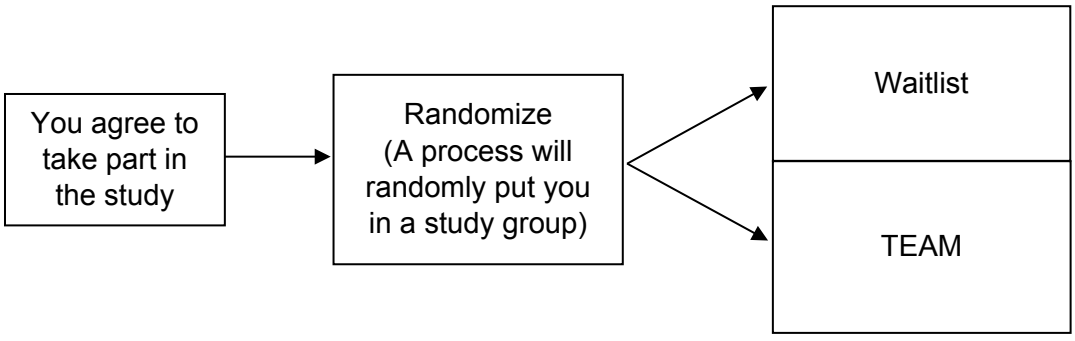
Baseline
At the baseline visit, you will be asked questions about your health, lifestyle, health knowledge, social support, and medications. You will have your height, weight, and blood pressure taken and will have some blood drawn (about 1 tablespoon) to check your cholesterol, triglyceride, and HbA1c levels.

If you are not able to come in to the office for an in-person visit, we may send personnel to your home to complete the blood draw, you may go to a UH outpatient lab near your home or if you do not live hear a UH outpatient lab, you can complete the blood draw at a LabCorp location. If none of these options are feasible, we may use lab values from your medical record from lab work you had done by another doctor. In addition, if you are not able to come in to the office for an in-person visit, we will have you take your blood pressure at home or have the study personnel who does your at-home blood draw take your blood pressure, and we will ask you to self-report your height and weight.

You will be randomized to either the TEAM or Waitlist intervention.

The baseline visit will last about 60 minutes.

Randomization/Study Intervention
If you participate in this study, you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. Neither you nor study staff will select the group to which you will be assigned. The study staff will let you know which group you are in.



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Schedule of Assessments and Events

	Screen	BL	3 Month	6 Month	9 Month	12* Month
Estimated time requirement of visit	**60 min**	**60 min**	**60 min**	**60 min**	**60 min**	**60 min**
Informed consent	**X**					
Blood Pressure		**X**	**X**	**X**	**X**	**X**
Demographics	**X**					
Randomization		**X**				
Questionnaires about your stress, health, discrimination, health risks, etc.		**X**	**X**	**X**	**X**	**X**
Questionnaires about your knowledge of stroke, self-efficacy, and your social support		**X**	**X**	**X**	**X**	**X**
Questionnaires about your health and lifestyle such as medications you take, diet, exercise, smoking, substance use, etc.		**X**	**X**	**X**	**X**	**X**
Blood draw: • cholesterol • HDL, LDL • triglycerides • HbA1c		**X**		**X**		**X**
Height (at BL) and Weight		**X**		**X**		**X**
TEAM intervention for the experimental arm		→	→	→		
TEAM intervention for the waitlist arm					→	→
Participant satisfaction				**X**		
Qualitative Assessment (for subgroup of participants)		**X**		**X**		

***Individuals who join the study on or after August 1, 2024 will not be assessed at 12 months. Their participation will last only 9 months.**

Educational Intervention (TEAM):

If you are randomized to the TEAM group, you will begin the intervention within the next couple of weeks. If you are randomized to the Waitlist group you will begin the intervention in about 6 months. No matter which group you are randomized to, you will still continue with the regular care you get from your usual provider throughout your participation in the study.

There are three parts to the intervention:

1) An individual initial session - in this session, the research study nurse and the Peer Educator (PE) or Peer Educator Dyad (PED – another African-American man who has had a stroke along with his care partner) will meet with you and your care partner (if applicable). The initial session will cover introductions and an explanation about what to expect from the intervention. This session will last about 1 hour.
2) Five group sessions – the group will consist of 6-10 stroke survivors (and their care partners as applicable) and will be held approximately 4 weeks, 6 weeks, 8 weeks, 10

weeks, and 12 week after you are randomized. The sessions are co-lead by the research study nurse and the PED. These sessions will teach about how to reduce your stroke risk. Each session lasts about 1 hour.

3) Six brief telephone sessions - after the conclusion of the 5 TEAM group sessions, the research study nurse and the peer educator will take turns calling you. Calls will be every 2 weeks for 12 weeks. The calls will be about what you learned in the sessions, will provide you with some support in working at your health goals, and will help link you with other care providers if needed. The nurse will make 3 calls and the peer educator will make 3 calls. Each call will only be about 10-20 minutes long.

You can participate in the individual initial session and the group sessions over the internet or by phone if you are not able to attend in person.

Follow up assessment visits
You will return for assessment visits that will be similar to the Baseline visit at about 3 months, 6 months, 9 months, and, if you join the study prior to August 1, 2024, 12 months after the Baseline visit. At these visits you will be asked questions about your health, lifestyle, health knowledge, social support, and medication. You will have some blood drawn (about 1 tablespoon) to check your cholesterol, triglyceride, and HbA1c levels.

The 3, 6, 9, and 12 month visits will each last about 60 minutes.

Follow up assessments visits can be done over the internet or by phone if you are not able to attend in person. If you are not able to come in to the office for an in-person visit, we may send personnel to your home to complete the blood draw or you may go to a UH outpatient lab near your home. If none of these options are feasible, we may use lab values from your medical health record from lab work you had done by another doctor. In addition, if you are not able to come in to the office, we will have you take your blood pressure at home or have the study personnel who does your at-home blood draw take your blood pressure, and we will ask you to self-report your height and weight.

Optional Qualitative Interviews
In addition to the study visits and educational intervention, you may be asked to participate in two additional interviews, one within a couple of days of your baseline visit and one on or within a couple of days of your 6 month assessment. During these interviews you will be asked questions about topics including your stroke/TIA, how you experience your recovery, your health behavior, how you communicate with others and

your doctor, and how you are doing in the study. These interviews can be done over the internet or by phone if you are not able to attend in person.

These interviews will be video-recorded. You will be asked to sign a separate waiver form to allow us to record the interview. Participation in these qualitative interviews is voluntary and you can decide whether or not you want to participate. You do not have to participate in the qualitative interviews to be able to participate in the main study.

Depending on when you are starting this study, we may already have enough people who have agreed to participate in the additional interviews. If we are no longer accepting people into the additional interviews, we will tell you.

Please indicate your choice by checking one of the boxes below:

Yes, I am willing to participate in the additional interviews if the researchers ask me to and I understand that these interviews will be audio-recorded.
No, I am not willing to participate in the additional interviews and I understand that I may still participate in the main part of the study.
I have been informed that the study is not open for this part.

Detailed Risks

Some of the questions in the surveys and questionnaires may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

The timing and duration of the group sessions may be inconvenient and there is the possibility that you may feel tired after participating in these group sessions.
Because you will meet other individuals who have had stroke or TIA, there may be some loss of confidentiality and other people will find out that you had a stroke or TIA. All participants will be reminded that it is very important to respect the privacy and confidentiality of everybody in the group.

There is minor pain associated with blood drawing. Some individuals who have blood drawn will experience bruising at the site of the blood draw. There is a chance you may feel faint or dizzy from having your blood drawn.

Financial Information

There is no cost to you or your insurance for participation in this study.

If you join the study prior to August 1, 2024, you will receive $50 each for completing the screen, baseline, 3-month, 6-month, and 9-month assessment visits and $100 for the 12-month assessment visit. Total possible compensation for participation in this study is up to $350.

If you join the study on or after August 1, 2024, you will receive $50 each for completing the screen, baseline, 3-month and 6-month assessment visits and $100 for the 9-month assessment visit. Total possible compensation for participation in this study is up to $300.

If you participate in the qualitative interview part of the study you will receive an additional $50 for each qualitative interview you complete (up to an additional $100). During your participation in the TEAM intervention sessions, you may be given small items of insignificant value (e.g., $5 gift card, pens, notebooks, key tags, lanyards, mini calendars, etc.) for answering questions and/or participating in group discussion.

If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits that you have completed. Payment will be made by check mailed to you after the visit is complete, a reloadable debit card, a gift card or direct deposit. If you do not have a bank account to cash the check or are unable to use a debit card or gift card, the research assistant will discuss alternative payment methods with you.

You will also receive assistance with transportation to each of the assessment visits and the intervention visits in the form of a bus pass or a parking pass.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS. You will be issued a 1099-Misc form only if payment exceeds $600 from all studies in which you are participating, in a fiscal year.

Contact for Future Research

Our study team may have additional research studies in the future. We would like your permission to contact you in the future if we think you could be a potential participant in one of our studies. Please check one of the boxes below that indicates your choice to be contacted for future research.

- ❑ Please contact me by _____ for future research opportunities.

- ❑ Please do not contact me for future research opportunities.

Clinical Trial Information
U.S. NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL TRIAL DATABASE: 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 website at any time to find out information about the trial and basic results.

Student/Employee Rights
Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor.

Confidentiality
The records of this research will be kept confidential. Any time information is collected, there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.
In any sort of report we might publish, we will not include any information that will make it possible to identify a participant. Research records will be kept in a locked file and access will be limited to the researchers, the institutional review board responsible for protecting human participants, and regulatory agencies.

The only exception to this promise of confidentiality is that we are legally obligated to report evidence of child abuse or neglect.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

All audio recordings will be destroyed at the end of the study. If you are selected for the qualitative interview, you will be asked to sign a separate consent form called GM-23 that allows us to use this information. If you do not agree to being recorded and sign the GM-23, the investigators will need to determine whether you will be able to participate in the qualitative interview part of the study or not.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information,

documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

Privacy of Protected Health Information (HIPAA)

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled “Reducing stroke risk in African-American men - TEAM2 (RCT)” and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Martha Sajatovic, and the research study staff to collect and use your PHI, you must sign this authorization form.

You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you:

- your name, initials, address, telephone number, date of birth and other demographic information;
- your medical history and the name of your physician(s) and locations where you received any treatment; and
- numbers or codes that identify you such as your social security number, and medical record number.

This PHI will be used to help evaluate the TEAM intervention and to contact you for study activities and to pay your stipend. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research:

- Case Western Reserve University, including staff from the Department of Psychiatry, Department of Neurology, and the School of Nursing
- University Hospitals, including the staff from the Department of Neurology, other staff from the Principal Investigator's medical practice group, the Center for Clinical Research and the Law Department
- Government representatives or Federal agencies, when required by law

It is possible, that in the future, additional research sites may be added. In this event, your PHI that was collected during this research project may be shared with research personnel at these additional sites.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your

authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to:

Martha Sajatovic, M.D., Department of Psychiatry – 7th floor
Case Western Reserve University, 10524 Euclid Ave., Cleveland, OH 44106

If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.
The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of Your Rights as a Participant in a Research Study
Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of Your Study Records
Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study

sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact Information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator, Dr. Martha Sajatovic, can also be contacted at 216-844-2400. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

x			
Signature of Participant		Date	Time
x			
Printed Name of Participant			

x	

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Signature of person obtaining informed consent	Date	Time
x		
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