Official Title: Reducing Stroke Risk in African-American Men

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Protocol Title: ***Reducing stroke risk in African-American men (TEAM2)***

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Background and Rationale

Overview: Stroke has a greater impact on African Americans (AA) than any other U.S. racial group[65] and a particularly malignant effect on AA men.[66] Risk factors that predispose AA men to early stoke are the same risk factors that complicate care and increase risk for stroke recurrence (hypertension, hyperlipidemia, diabetes).[67] Interventions to improve post-stroke outcomes and reduce risk for future stroke include evidence-based pharmacotherapies,[68] and behavioral modifications such as smoking cessation, change in diet, weight loss, exercise and stress management.[68] As AA men underutilize evidence-based post-stroke care, there is a critical need for interventions that maximize facilitators and minimize barriers to care. Interventions that improve post-stroke care for AA men and reduce stroke risk factors have the potential to close the health disparity gap between AA men and other Americans.

AA are more likely to experience stroke, AA men are most heavily impacted. AA typically have higher stroke risk profiles compared to the general population, including higher prevalence of obesity, lack of exercise, cigarette smoking, excess sodium, lower income, reduced access to health care and stress.[69-72] A systematic review emphasized the contribution of social determinants to stroke risk in AA, noting that perceived racial discrimination contributes negatively and significantly to hypertension risk.[73] Literature supports the notion that systematized inequalities compound individual biological risk factors and contribute to stroke burden.[73-75] Not surprisingly, AA are at higher risk for a first-time stroke at an earlier age compared to NHW.[76, 77] AA men have age-adjusted stroke mortality rates that are 43.7 percent higher than NHW men.[66]

One-quarter of strokes that occur each year in the U.S. are recurrent events.[78] Recurrent stroke risk increases over time and 25% of stroke survivors will die of a recurrent stroke.[79] After TIA, stroke risk increases 12-fold.[80] A recent analysis of a large, multicenter clinical trial focused on stroke and cardiovascular event recurrence evaluated 3,470 (20% AA) recent stroke patients aged ≥35 years and followed them for 2 years.[81] AA patients (enrolled in the US and United Kingdom) with a recent stroke had an approximately 60% higher risk of recurrent stroke compared to their white counterparts.[81] This difference was explained by a substantially greater vascular risk factor burden in the AA patients and suggested that targeted care for better risk factor control after a stroke in AA patients may help close the disparity gap in racial stroke outcomes.

AA are less likely to be discharged post-stroke to rehabilitation/therapy-intensive settings. While some stroke patients leave the hospital to enter rehabilitation settings with intensive physical and other types of therapy, AA are more likely to be sent home post-stroke. [17] Ottenbacher[17] reported that 76% of minority groups are discharged home compared to NHW (66%) post-stroke patients. Patient and family preferences play a large role in discharge planning and AA tend to view nursing homes more negatively than NHW.[82] Social supports for AA stroke patients may facilitate home-based care and reliance on informal caregivers. Alternatively, limited financial resources may promote the use of informal (unpaid) caregivers. [17] Once discharged from acute-care after a stroke, AA have higher rates of hypertension, obesity, diabetes and inactivity compared to NHW.[67] Given the fact that AA stroke survivors are more likely to be at home as opposed to a re-habilitation setting, spouses and other family are likely to be involved with post-stroke care.

Evidence-based therapies improve health outcomes, but are under-utilized by AA men. Major areas of care for all stroke survivors include (1) managing stroke risk factors/comorbid illness and treating medical complications; (2) training to enhance independence; (3) supporting psychosocial coping and adaptation; (4) promoting community reintegration; and (5) enhancing quality of life.[83] The American Heart Association Guidelines[78] prioritize management of specific modifiable risk factors known to be disproportionately common in AA, such as hypertension, diabetes, hyperlipidemia, smoking, alcohol use, obesity, and inactivity. Evidence-based therapies mitigate the devastating consequences of stroke [34] and can improve health outcomes.[84, 85]

Patient engagement with behavioral recommendations to reduce stroke risk such as healthy diet, exercise, and smoking cessation can be difficult.[86] Unfortunately, AA have low stroke risk factor awareness and low use of therapies that might prevent future stroke.[42, 87-90] In the REGARDS (REasons for Geographic And Racial Differences in Stroke) study,[91] AA were more aware of their hypertension than NHW, but among those treated, hypertension was less likely to be controlled. Illustrating the challenge in reducing stroke risk and burden among AA men, a South Carolina study found an overall decline in the incidence of stroke since 2000, with the notable exception that young AA men are the only group to have had an *increase* in stroke (of 17.5%) in the period from 2000 to 2010.[92] Long-term stroke survival also continues to be worse among AA men aged 45 to 64, with a 36% mortality after 5 years compared with 25% for NHW men.[4, 93] Kronish and colleagues[23, 26] conducted one of the few interventions targeted to AA, the Prevent Recurrence of All Inner-city Strokes through Education (PRAISE) trial.[85] While participation in PRAISE was associated with reduced BP in individuals who had experienced stroke or TIA within the past 5 years, the study sample was predominantly female.

In summary, AA men experience a disproportionate burden from stroke compared to other Americans, and there are no widely used post-stroke risk-reduction approaches which specifically target AA men. Interventions that are acceptable and effective have potential to close this important health disparity gap and are urgently needed.

The proposed research features a nurse-led, person-centered, holistic intervention that takes advantage of existing strengths in AA families/communities. TEAM uses peer educator dyads (PEDs) to provide support and model behaviors. The PED consists of an AA man peer educator (PE) with experience in managing his own stroke risk and a care partner. A care partner is someone who is the family member, friend or other individual of someone who has had a stroke or TIA. A care partner can be associated with a PE but they do not have to be. PEs and care partners will be matched depending on schedules and availability and may not always be members of the same household. The nurse and PED co-deliver TEAM to an AA male patient who has experienced stroke or TIA. Patients are also encouraged to include a family, friend, or other individual important his stroke recovery in the TEAM programming. The intervention is a practical approach suitable for implementation in specialty, primary care or community settings, and has the potential to reverse the unacceptably high morbidity seen in AA men due to stroke-related disorders. The proposed study will be investigated in two specific aims:

Specific Aim 1: To test the effects of TEAM vs. WL on systolic BP and serum high–density lipoprotein cholesterol (HDL) in AA men with stroke or TIA within the last 10 years in a prospective, RCT format.

H1: AA men with stroke or TIA (n= 80) who participate in TEAM will have significantly lower systolic BP compared to AA men with stroke of TIA (N= 80) who participate in WL at 6-month follow-up

H2: AA men with stroke or TIA who participate in TEAM will have significantly higher HDL compared to AA men who participate in WL at 6-month follow-up

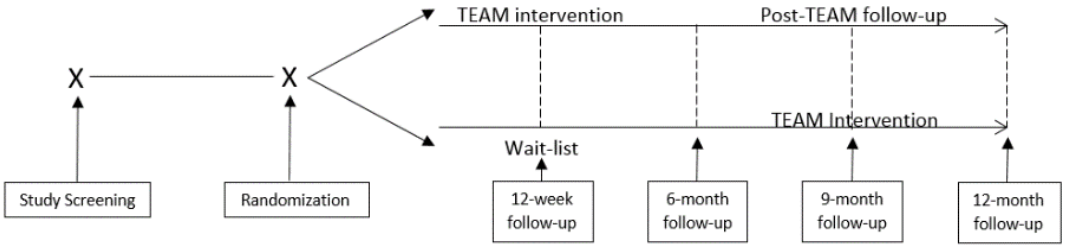
Specific Aim 2: To test if process elements of self-management (stroke knowledge, self-efficacy, perceived social support) and proximal health behaviors (taking medications to reduce stroke risk factors, diet, exercise and smoking) mediate TEAM vs. WL's impact on primary and secondary health outcomes (systolic BP, diastolic BP, serum lipids, HbA1c) over a 12-month time period.

Secondary Aims: We will assess the intervention's impact on health outcomes while considering contextual variables such as stress, discrimination, depression, anxiety, social roles, and health literacy. Qualitative evaluations will be conducted to confirm self-management barriers and perceived strengths or limitations of the intervention that will inform future implementation and scale-up should these RCT findings be positive. An anonymous survey of study staff will assess barriers to study recruitment, how common the barriers are, and how the team addressed or resolved those barriers to reach enrollment goals.

Study Design

The proposed project is a 6-month prospective Randomized Controlled Trial evaluating the effects of **T**arg**E**ted M**A**nage**M**ent Intervention (TEAM, N=80) vs. wait-list (WL, N=80) control in African American men who have experienced a stroke or TIA within the past 10 years.

Figure 1: Study design



Study Procedures

To optimize enrollment and retention as well as collect information on longer-term trajectories of outcomes, individuals randomized to TEAM will be followed for a total of 12 months (baseline to 6 months for the initial evaluation and 6 to 12 months to evaluate sustainability of the TEAM intervention) for those consent before August 1, 2024 and 9 months for those who consent on or after August 1, 2024. Individuals consented on or after August 1, 2024 who are randomized to TEAM will be followed for a total of 9 months (baseline to 6 months for the initial evaluation and 6 to 9 months to evaluate sustainability of the TEAM intervention). Individuals consented on or after August 1, 2024 and are randomized to the WL control group will receive the TEAM intervention after the 6-month follow up time point. The primary health outcome will be change in systolic BP, while secondary health outcomes include change in other biologic parameters of stroke risk including diastolic BP, cholesterol/lipids, triglycerides, BMI, and glycemic control for diabetics. Exploratory analyses will evaluate how contextual factors (age, individual and neighborhood stress, racial discrimination, perceived health, depression, anxiety, social role, health literacy, and CVD-related factors), process factors (stroke knowledge, self-efficacy, perceived social support), and proximal health behaviors (exercise, smoking, and tobacco/substance use) may impact the primary and secondary distal health outcomes. Qualitative assessment will evaluate TEAM and WL control from both the perspective of AA men and their care partners. Being able to provide the TEAM approach using a wait-list format provides an opportunity for all participants to eventually receive the TEAM intervention. By extending the observation period to 12 months (9 months for those consented on or after August 1, 2024) we will see if TEAM effects are sustained over time.

Participants: Participants will be recruited from clinical and community settings using previously successful approaches in enrolling and retaining minority and other historically under-served participants.[103-105] As in the NINR-funded pilot, involvement of care partners will be encouraged, but is optional and a key thrust of TEAM is emphasizing patient self-management and minimizing burden on care partners. Care partners will be identified by AA men as being someone who is an important individual in their support network and involved in their stroke recovery.

Potential PEs and PE care partners will be referred by study investigators or other colleagues of the PIs who will talk with the potential PE and ask if they and their care partner are interested in talking with the study team about the opportunity to be a PED. If the potential PE is interested, a member of the study team will contact them and make arrangements for them to meet with one of the PIs to determine if they and their care partner would be a good fit for the PED role. If a potential PE is interested in participating but does not have a care partner, they can still participate and will be matched with a PE care partner who does not have an accompanying PE.

Inclusion and Exclusion Criteria

Once a referral has been made, either by self or clinician referral a research assistant will telephone the potential subject, give a brief description of the study, and invite them to an appointment to assess their eligibility. Participants who have a care partner (i.e., someone who is an important individual in their support network and involved in their stroke recovery) may also participate in the group sessions. Individuals who provide informed consent will then proceed with screening and enrollment.

	Inclusion Criteria for RCT participant
1.	Age range: ≥ 18 years old

2.	Self-identified African American male
3.	Have had a stroke or TIA within the past 10 years based on date of hospital discharge from an acute stroke program or Emergency Room/physician visit for TIA
4.	Barthel Index (BI) score of ≥ 40
5.	Able to participate in group sessions
	Inclusion Criteria for Care Partner participant
1.	Age range: from 18 to 90
2.	Able to participate in group sessions
	Inclusion Criteria for Peer Educator
1.	Age range: from 18 to 90
2.	Self-identified African American male
3.	Have had a stroke or TIA
4.	Able to participate in group sessions
	Inclusion Criteria for Peer Educator Care Partner
1.	Age range: from 18 to 90
2.	Able to participate in group sessions
3.	Is either a family member, friend or other individual who is important in an enrolled peer educator's stroke recovery OR the family member, friend or other individual of someone who has had a stroke or TIA and is/was important in their stroke recovery
	Inclusion Criteria for Recruitment Barriers Survey Participants
1	Age range: from 18 to 90
2	Current or former TEAM 2 study staff
3	Involved in the planning and/or implementation of study outreach and recruitment activities

	Exclusion Criteria for RCT participant
1.	Individuals who are unable or unwilling to provide written informed consent
2.	Individuals who have had stroke due to sickle-cell disease
	Exclusion Criteria for Care Partner participant
1.	Individuals who are unable or unwilling to provide written informed consent
	Exclusion Criteria for Peer Educator
1.	Individuals who are unable or unwilling to provide written informed consent
2.	Individuals who have had stroke due to sickle-cell disease
	Exclusion Criteria for Peer Educator's Care Partner
1.	Individuals who are unable or unwilling to provide written informed consent
	Inclusion Criteria for Recruitment Barriers Survey Participants
1.	Individuals who are unable or unwilling to provide consent

Number of Research Participants

We will enroll 160 RCT subjects at UHCMC. There will also be up to 20 care partners enrolled in the qualitative interview at UHCMC.

There will also be up to 6 PE and Care Partner Dyads (PEDs).

We will enroll up to 12 individuals in the recruitment barriers survey portion of the study.

Recruitment Methods

Patients will be recruited from inpatient, ambulatory services and from the community by a variety of methods:

1. Study staff will inform the University Hospitals of Cleveland Medical Center (UHCMC) clinical psychiatry providers about the study.
2. Study staff will also present information about the study to the staff at local Community Health Clinics and other organizations serving persons with these health conditions. After presenting the study in these group and individual settings, the study staff will maintain regular contact with staff at these organizations to inquire about new referrals.
3. IRB-approved recruitment fliers will be posted and distributed with permission of staff at Community Health Clinics and other organizations serving persons with these health conditions.
4. IRB-approved text that will be posted on the internet, such as ResearchMatch, on social media (Facebook, Twitter and Instagram pages of UH departments and/or the Center for Clinical Research) or UH department research websites. We will also recruit via IRB approved bus, radio and newspapers ads, and mass mailings which are being done in coordination with UH Marketing & Communications and Brokaw ad agency.
5. Recruitment will be done by oral request to patients coming for regularly scheduled clinic visits at UHCMC. Requests for participation may be initiated by a clinic staff member, by a research associate on site, or in some cases may be initiated by patients themselves.
6. We will also check UH, MetroHealth Medical Center and Southwest General electronic medical records as well as the UH Cutler Center for Men patient database to identify potential participants, using age, race, and, for the UH, MetroHealth Medical Center and Southwest General electronic medical records searches, stroke/TIA diagnosis in the past 10 years, as search criteria. Address and phone numbers will be collected so that they can be contacted (by letter or email, followed by a phone call). The letters will mention specifically that individuals can opt out of the follow up phone call. Potential participants who do not opt out of the follow-up phone will be contacted and, if they express interest in the study, a screening visit will be scheduled. Up to 2 attempts will be made to contact the potential participant. Research personnel will leave a voicemail if the person does not answer. For those participants who cannot be contacted, refuse participation, or otherwise do not qualify for the study, only aggregate numbers will be retained to keep track of recruitment efforts. The personal information will only be kept for as long as necessary (i.e. until the participant is enrolled or documented as a pre-screen failure). We will request a partial waiver of HIPAA to be able to collect PHI for recruitment purposes.
7. Patients may also be recruited under the local Behavioral Health Research Group (BHRG) Prescreen protocol (STUDY20210888) as developed by the proposed study PIs.
8. We will use MyChart recruitment to identify interested individuals and follow up their expressed interest with a phone call and/or email or letter.
9. We will contract with Trialfacts, a clinical trial and health research participant recruitment service provider, to recruit potential participants. The promotional materials developed for this study are attached to the application. Recruitment occurs in the following ways:
    a. Web Ads: The study is posted their website,
    b. Promotional Ads & Content: They launch live campaigns on various advertising platforms. The primary platform is normally Facebook, with secondary or other potential platforms included. These ads use video and/or images
    c. Email Newsletter: They add the study to their email newsletter that gets sent to their targeted database of potential participants.
    d. Landing Page: Once a potential participant clicks on an ad or newsletter, they navigate to a dedicated study page (the landing page) to find out more information about the study.
    e. Questionnaire: Once the potential participant is interested, they then click to complete the pre-screen questionnaire. This provides logic to make sure the participant fits the criteria of the study.
    f. Confirmation Text and/or Email: Once the potential participant fails or passes the questionnaire, they will receive a confirmation email or text message confirming next steps.
    g. We receive the individuals information via email and via an update to a prescreen referral spreadsheet to which only study staff is granted access. We will then reach out to potential participants to tell them more about the study, answer any questions they have, and continue on to consent and enrollment for those who are interested. We may use Trialfacts phone appointment system to schedule screening appointments for some individuals. This system allows interested

individuals to view study staff availability and schedule a day and time for screening via the Trialfacts website.

All individuals with a history of stroke/TIA who are referred will be considered for possible inclusion in the study. A Screening Form for each patient will be completed regardless of whether the patient is ultimately enrolled. The form will detail reasons for exclusion, allowing an estimate of sample generalizability.

Patients recruited in response to an IRB-approved recruitment method may be prescreened under the IRB-approved protocol, "Prescreening and Recruitment for the Mental Health Effectiveness Research Program and Neurological and Behavioral Outcomes Center" (MHERP/NBOC Prescreen) [IRB # 03-10-09].

As in previous projects by these investigators, a minority advisory board will be created with the specific purpose of increasing community awareness of stroke risk factors in AA, engaging the community, and promoting research participation. A key focus of the TEAM2 Advisory Board (TAB) will be giving the team input and suggestions on reaching out to and engaging AA communities. The TAB includes health professionals, administrators, community activists and AA patients and families with lived experiences with aging-related brain-health conditions.

Study staff will be recruited to participate in the recruitment barriers survey via email with an anonymous link to the study information sheet and survey.

PEs will be invited to participate in a panel at the University Hospitals 2025 Stroke Update and 18th Neuroscience Nursing Symposium. At a regularly scheduled quarterly meeting in July, the PI shared with the 2 PEs that are co-facilitating the intervention sessions for current cohorts that the PI may be inviting them to participate on the panel pending regulatory (IRB) requirements and Peer Educator time/interest. Once IRB approval is obtained, the PI will formally invite those PEs to participate in the panel, as well as one other PE who has co-facilitated other cohorts in the past. Those who wish to participate will then be consented per the "*Research Panel Participation consent process"* section on page 8.

Setting

1) The sites and locations where your research team will conduct the research:
   - The PI's research offices at the W.O. Walker Center, 10524 Euclid Ave.
   - The Stroke Center in the UH Department of Neurology at Bolwell Building, 11100 Euclid Ave.
   - UH Otis Moss Jr. Health Center, 8819 Quincy Avenue
   - The location of the Cleveland Stroke Club meeting at Select Medical, 11900 Fairhill Road
   - The CWRU School of Nursing Health Education Campus, 9501 Euclid Avenue and Health Research Campus, 2120 Cornell Road

2) Where your research team will identify and recruit potential research participants:
   - From UHCMC and the community (see details above).

3) Include the physical location where research procedures will be performed.
   - The PI's research offices at the W.O. Walker Center, 10524 Euclid Ave.
   - The Stroke Center in the UH Department of Neurology at Bolwell Building, 11100 Euclid Ave.
   - UH Otis Moss Jr. Health Center, 8819 Quincy Avenue
   - The location of the Cleveland Stroke Club meeting at Select Specialty Hospital, 11900 Fairhill Rd, Cleveland, OH, 44120
   - The CWRU School of Nursing Health Education Campus, 9501 Euclid Avenue and Health Research Campus, 2120 Cornell Road
   - UH DCRU
   - UH Outpatient Labs
   - Participants' homes
   - Other private venue of participants' choice, including mental health center/physician's office, private/ closed room in local library, etc.

- LabCorp, Quest Diagnostics or another lab facility of the participants choice

The consent process may be conducted remotely via video conferencing (UH Zoom, CWRU restricted Zoom or WebEx) and via REDCap (individual link emailed directly to the participant) if necessary. Follow-up visits, with the exception of BP evaluation and laboratory testing, may also be conducted via video conferencing (UH Zoom, CWRU restricted Zoom or WebEx) or phone and REDCap survey (individual link emailed directly to the participant) in the event an in-person visit is not possible. In addition, TEAM intervention sessions and qualitative interviews may also be conducted remotely via telephone or internet participation if needed.

Consent Process

The 160 participants recruited to the study (80 individuals in TEAM, 80 individuals in WL) and the up to 20 care partners recruited for the qualitative interview will provide written informed consent for the project at the PI research offices at the W.O. Walker Center, at a private venue of participants' choice, including mental health center/physician's office, private/ closed room in local library, etc., or electronic written consent in REDCap (individual link emailed directly to the participant). Potential subjects will be provided with either a physical copy of the consent form or an emailed electronic copy of the consent form, which they will be asked to read and review fully. Following this, the researcher will ask whether the participant has any questions, and then orally summarize all the points covered in the informed consent, again inquiring if there are any questions. Prospective participants will be asked to explain what the study will involve in their own words to confirm their understanding. A copy of the signed consent form will be provided to each subject. The research assistant will then record that the consent was obtained and that the decision to participate in the research was "informed." Up to 20 care partners of TEAM and of WL participants will be invited to participate in a 6-month follow-up qualitative interview, for which they will provide informed consent using the same procedure as outlined above for the TEAM or WL participants. Up to 6 PEs will also participate in qualitative interviews and quantitative data collection and their care partners will participate in qualitative interviews. Care partners, PEs and PEDs will also provide informed consent and have their identity verified using the same procedures outlined above. No study procedures will be conducted until the signed consent (page) is received by the study team.

Virtual Consent Process

The potential participant will be in possession of the full IRB-approved informed consent document. The study team will arrange a mutually convenient time for a full informed consent process with the potential participant. Once both parties are able to see each other over the virtual visit, the next step involves completing identity verification (details must be documented in the study team records). The potential participant is asked his/her full name and DOB, and is asked to display his/her driver's license or if not available, any state or government-issued picture identification card. If they do not have picture identification, they will be asked to provide the last four digits of the social security number, their date of birth and one of the following: account number, street address, insurance carrier name, insurance policy number, medical record number, birth certificate or insurance card. This alternate process of remote consent is for the duration of the pandemic only.

If the bandwidth or connection does not permit a virtual visit with audiovisual capabilities, the potential participant can take a picture of their face (also known as a "selfie") and a picture of their photo ID and email* both of these photographs to the study team's University Hospitals e-mail address to verify identity. Information from the potential participant will not be sent to the personal device or personal email of the study team member, and a study team UH email only be used if this process is needed. Once identity verification is completed, the full informed consent process will occur in real-time during the virtual (or audio) visit. If the potential participant decides to enroll, an electronic signature will be obtained during the virtual visit. We will utilize the process available in REDCap. If the potential participant is unable to utilize the electronic format for signature, the prospective participant can sign a paper copy during the virtual visit, we will take a picture of the signature page, and email that photograph to the study team's University Hospitals e-mail address at the end of the virtual visit. Alternately he/she will sign the paper consent and mail/fax/scan it in to the study team. We acknowledge that a signature will be received/documented before study procedures begin.

Recruitment Barriers Survey consent process

We will use study staff rosters to identify potential participants. A recruitment email with a link to the study information sheet will be sent to these individuals. Those interested will click the link where they can review the

study information sheet in REDCap. If they wish to continue, they will click “agree” at the end of the information sheet, and then they will be directed to the anonymous survey.

Research Panel Participation consent process
Peer Educators who are interested in participating in the University Hospitals 2025 Stroke Update and 18th Neuroscience Nursing Symposium will be sent an information sheet about participation in the panel, either electronically or on paper, depending on their preference. They will be provided with enough time to review the information sheet have any questions they may have answered. They will then check either that they agree or that they do not agree to participate. They will also sign the UH Marketing and Communications HIPAA release form. Research personnel will send the Peer Educator a copy of the completed information sheet and signed HIPAA release form.

Treatment randomization: After informed consent, screening and baseline procedures, individuals will be randomized on a 1:1 basis to either TEAM or WL control. Block randomization with block sizes ranging randomly between 4 and 8 consecutive patients will be employed to ensure that equal numbers of TEAM and WL control participants occur within strata and are balanced with respect to relevant comorbidity (diabetes and previous stroke). The randomization list will be computer-generated by personnel within the biostatistics core of the CWRU Neurological and Behavioral Outcomes Center who are not members of the study staff.

Schedule of study procedures: Table 1 outlines study procedures. After screening and enrollment, each research participant consented prior to August 1, 2024 will be assessed 5 times: at baseline, at 12 weeks/3 months (after the completion of the TEAM group sessions), and at 6, 9 and 12 months follow-up. Those consented on or after August 1, 2024 will be assessed 4 times: at baseline, at 12 weeks/3 months (after the completion of the TEAM group sessions), and at 6 and 9 months follow-up. Qualitative interviews will be conducted at base-line and 6 months. Data will be obtained from patient interviews, BP evaluation, and laboratory testing. Participants will be reimbursed $30 for the first 5 (or 4 where applicable) research assessments and $100 for the final assessment. All assessments for a single participant will be completed by a single rater research assistant, trained to IRB approved protocol except for the dietary assessment, which will be conducted by DCRU staff, and the blood draw. The blood draw may be done by DCRU staff at the DCRU or W.O. Walker Center, at the participant’s home by trained personnel or at a UH outpatient lab. In the event none of these are feasible, we will use lab values from the participant’s health record that were collected by another provider around the same time as a scheduled study visit. It is expected that a patient assessment will take approximately 60-90 minutes for the screening and approximately 30-60 minutes for the baseline and follow-up assessments. The patient interview portion of the study visits may be conducted via internet participation or over the phone and via REDCap survey (individual link emailed directly to the participant) if necessary. BP evaluations may be done in-person by DCRU or other study staff, at the participant’s home by trained personnel, or by study participants at their homes using a BP monitor provided to them by the study. In addition, if necessary, TEAM intervention sessions may be conducted remotely via telephone or internet participation.

Peer Educators will complete quantitative interviews at screening and annually during their involvement in the trial. Quantitative data will include demographic variables, perceived health status, self-efficacy, stroke knowledge, blood pressure, and height/weight. The total assessment battery will not exceed 60 minutes at each time-point. The PEs will complete qualitative interviews at some point after they have co-led at least one TEAM group. Care Partners of PEs will also complete qualitative interviews at the same time point as the PE.

Study staff will also invite up to 3 Peer Educators to participate in a panel at a research symposium, University Hospitals 2025 Stroke Update and 18th Neuroscience Nursing Symposium. The symposium is designed to present the current guidelines on the diagnosis, treatment and care of patients with cerebrovascular disorders based on the latest advances in the fields of neurology, neurosurgery, neuro-interventional, neuro-critical care, and neuroscience nursing. The symposium will be recorded and the recording will be posted to the Case Western Reserve University Continuing Medical Education website, The participant will be required to sign a HIPAA waiver from UH Marketing to participate in the panel and be recorded.

Participation in the panel is completely optional and is not part of the study activities. Interested Peer Educators will complete a separate consent process to participate in the research panel (see above). No additional data will be collected from these participants, and they will not receive compensation for this activity.

University Hospitals 2025 Stroke Update and 18th Neuroscience Nursing Symposium details:

- When- Friday, September 12, 2025, 7:15 AM - 5:15 PM,
- Where- Corporate College East, Cleveland, OH
- Audience- healthcare professionals
- Format of presentation the Peer Educators will participate in:
    - **Part 1 (30-40 mins)** Interventions Targeting Racial/Ethnic Disparities in Stroke Prevention and Treatment. Dr. Sajatovic will briefly review the literature and discuss where the field is as well as provide an overview of the TEAM project and results
    - **Part 2 (15-25 mins):** Panel discussion of TEAM participants. The panel will consist of TEAM 2 Peer Educators, the PI, Dr. Sajatovic and co-investigator, Dr. Sophia Sundararajan.

Qualitative interviews for both PEs and their care partners may be conducted via video conferencing if an in-person interview is not possible. In addition, blood pressure and height/weight for PEs may be done by the study participant using a home BP monitor provided to them by the study and self-reporting height/weight, or by using blood pressure, height and weight data found in the participant's health record that were collected around the same time as a scheduled study visit.

Measures: Baseline assessment will include demographic information as well as contextual, process, behavioral and health outcome factors relevant to the ISMT theoretical model. As noted in Table 1, measures will be repeated at 3, 6, 9 and 12-month follow-up except for laboratory testing, which will be conducted only at baseline, 6 and 12-month follow-up. Those consented on or after August 1, 2024 will not be assessed at 12 months. Their last follow up assessment for all measure except laboratory testing will occur at 9 months. The last laboratory testing follow up for these individuals will occur at 6 months. BP assessments will be conducted using standardized accepted procedures using the same arm each time for an individual participant.[114] The study measures approximate those done in the pilot TEAM study, and while relatively extensive, did not seem to present an undue burden for the pilot study participants.

Primary and secondary health outcomes: The primary health outcome comparison between TEAM vs. WL control will be change in systolic BP from baseline to 6-month follow-up. Additional biological markers indicative of stroke risk will include diastolic BP, cholesterol, HDL, LDL, triglycerides, BMI and glycosylated hemoglobin (HbA1c), a marker of relative glucose control over the past 3 months.

Contextual factors: Contextual factors will include variables known to contribute to racial health disparities as well as individual and health condition-specific factors that may impact the effects of TEAM on AA men. Individual perceived stress will be evaluated with the Perceived stress scale (PSS) [115, 116] a 10-item global health instrument that has been validated in the U.S. Neighborhood stress will be characterized using residential neighborhood codes from the regional Northeast Ohio Community and Neighborhood Data for Organizing (NEOCANDO) project, a set of data tools of the Center on Urban Poverty and Community Development housed at CWRU's Mandel School of Applied Social Sciences. The 29-item Patient-Reported Outcomes Measurement Information System (PROMIS) will evaluate perceived health status, a comprehensive self-rated measure that includes physical function, anxiety, depression, social role, sleep (we will only ask sleep quality question), fatigue and pain (we will only ask overall pain question).[117, 118] Racial discrimination will be assessed with the 9-item Everyday Discrimination Scale (EDS) developed by Williams and colleagues.[119] A recent literature review of studies evaluating association between racial discrimination and hypertension noted that the EDS was a widely used instrument on this topic.[73] Health literacy will be measured by the Rapid Estimate of Adult Literacy in Medicine short form (REALM-SF;[120] α=0.95) Physical health contextual factors will include medical burden [121, 122] measured by the Self Rated Charlson Comorbidity Index (CCI)[157] and cardiovascular index-(CVHI) [124]. Finally, we will be asking participants at each time point if they have received a COVID vaccine as we have integrated

some materials regarding COVID in to the manual. If a participant states they have received a COVID vaccine, we will stop asking them this question at subsequent follow up visits.

Self-management processes: Stroke knowledge will be measured with the Set of Stroke Knowledge Questions[156] to examine knowledge of key stroke risk factors and stroke prevention practices. Self-efficacy will be measured with the General Self-Efficacy Scale (GSE; α=0.76-0.90).[130, 131] Social support will be measured with the Medical Outcomes Study Social Support Survey (MOS-SS; α=0.91).[132, 133]

Proximal behavioral outcomes: We will assess specific health behaviors known to be important to stroke risk reduction, namely adherence with medication, exercise and avoidance of alcohol and recreational drugs. Medication-taking will be assessed in 2 ways: 1.) whether individuals are taking indicated stroke risk-reduction drugs (anticoagulants, antiplatelet agents, antihypertensive drugs, lipid-lowering drugs and drugs for diabetes) and 2.) self-reported medication adherence using the Tablets Routine Questionnaire (TRQ).[134] Exercise will be assessed with the Morgenstern Physical Activity Questionnaire (PAQ-M; α=0.87).[136] Smoking will be assessed with the Fagerstrom Test for Nicotine Dependence (FTND)[137, 138] while use of alcohol and other recreational drugs will be assessed with the National Institute on Drug Abuse (NIDA)-Modified Alcohol, Smoking, and Substance Involvement Screening (ASSIST; α=0.77)[140, 141] for adults, respectively.

Diet will be assessed utilizing the Nutrition Data System for Research (NDSR). The NDSR is a Windows-based nutritional analysis software program that was specifically designed for collecting and analyzing 24-hour dietary recalls. NDSR utilizes the multiple-pass approach of interviewing which permits the subject ample opportunities to fully recall their dietary intake over the specified time. The first pass consists of an initial food list (called a quick list) which contains minimal detail; the second pass includes probing of each food item listed in the quick list with respect to portion size, cooking methods, time food consumed, etc. The third pass is a final review of all clarified and detailed food items. All passes allow subjects to expand on details regarding their dietary intake. Recalls generally take 20 minutes and is done for 3 days. The NDSR will be administered by the Bionutrition staff at the DCRU. The baseline assessment will be in-person or over the phone if necessary and the follow-up assessments for Month 6 and Month 12 will be by phone.

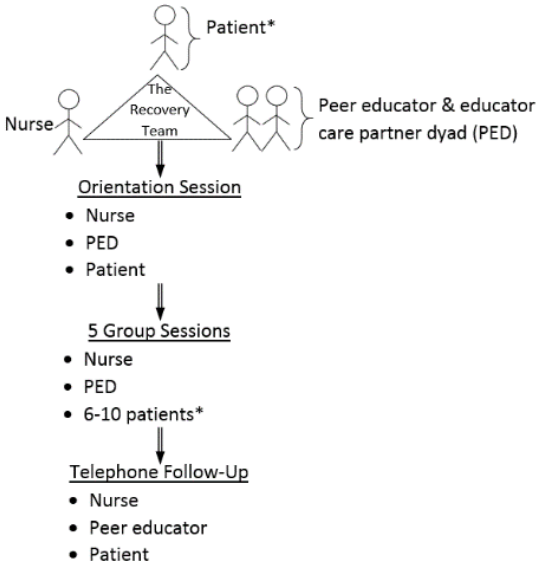
Both patients and their care partners will complete a brief participant satisfaction evaluation after the conclusion of the TEAM group sessions.

Qualitative Data Collection: While RCTs can demonstrate that an intervention leads to better outcomes, qualitative research can provide insight into "*why" and "how"* the intervention succeeds or does not succeed. Consistent with the concurrent nested sequential explanatory design, qualitative methods are embedded, or nested, within the quantitative method and seek information from different levels.[143, 144] In-depth interviews will illuminate actual self-management experiences from the perspective of AA men and will enrich[145] our understanding of the processes that impact RCT outcomes.[143, 144, 146-150] These data could facilitate the timing of future study data collection for the analysis of mediators: "What are the barriers to stroke risk reduction that are most challenging"; and "Does health behavior change[151] occur gradually or are there specific points at which individuals gain confidence and motivation to engage in risk reduction?" In addition, we will elicit perceptions regarding barriers/facilitators to modifiable risk as well as barriers/facilitators to overall recovery, and coping with stress and chronic illness. We will conduct interviews with 40 patients, with half of the respondents from the TEAM group and half from WL control (per conventional recommendations).[152] We will balance the selection of respondents by age, length of time since stroke or TIA, and diabetes comorbidity. We will also balance on relevant contextual factors that are known to influence stroke outcomes such as employment status, educational level and whether or not the interviewee has a care partner. Final determination of these factors will be made after review of early enrollment descriptive data (i.e. after the first 1-2 TEAM cohorts have been enrolled). Individuals who provide baseline data will again be interviewed at the 6-month follow-up time point to determine: 1) how they felt they were doing with managing their stroke risk factors, and 2) what they feel has been most helpful to them over the past 6 months in stroke recovery and managing risk factors. At the 6-month time point we will also interview 20 care partners (10 from TEAM and 10 from WL) to determine what they felt were the most important and helpful factors in managing stroke risk at the 6-month follow-up time point and how it might potentially be improved in the future. Qualitative interviews for both PEs and their care partners may be conducted over the phone if an in-person interview is not possible. There will also be up to 6 PEDs who will

complete a separate qualitative interview to help understand the perceived benefits of participating as a PED in this intervention. The qualitative assessment of PEs will mirror the assessment administered to African American men participating in the TEAM groups. We will also add some supplemental questions that evaluate PE satisfaction with their role such as how helpful they perceived the program to be in their own recovery, relative barriers to being a PED, and how this role might be improved in future efforts. The Care Partners of the PEs will complete the same qualitative assessment as the Care Partners of the study participants.

An adapted version of the interview guide used in the TEAM pilot will be used to elicit information on barriers/facilitators and other dimensions that help to identify strengths of the men as they engaged in the self- management process as well as challenges they encountered. The guide lists main topics and questions as well as suggested follow-up probes. All interviews will be video recorded, transcribed and imported into ATLAS qualitative software.

Figure 2: TEAM participants and encounters



Recruitment Barriers Survey
To assess barriers to recruitment for the randomized control trial, a brief one-time anonymous survey will be administered to those who provide consent via clicking "agree" at the end of the study information sheet.

TEAM Intervention. Building on previous work,[41, 61, 110] TEAM targets acquisition of self-management expertise and use of healthy behaviors that are intended to reduce stroke risk and burden [20, 21, 94, 95, 111-113] TEAM participants will continue in their regular medical care, supplemented by the TEAM intervention. Figure 2 depicts the composition of the recovery team (nurse, PED, patient) and the sequence of TEAM encounters. The format will be the same as that used in the NINR pilot except that there will be 5 rather than 4 group sessions to allow for more interactive discussion and a slightly slower pace. Follow-up phone calls will occur after the TEAM group session are complete. Components are as follows:

1) A 60 minute initial session in which the nurse and the PED meet with the patient who has experienced stroke or TIA. While participation of a care partner will be highly encouraged, patients will not be required to have a care partner participate. The initial session will cover introductions, orientation, and logistic planning. It will occur within approximately 30 days of study enrollment and prior to the first TEAM group session
2) Five 60-minute group sessions with 6-10 stroke survivors (and their care partners as applicable) held approximately 4 weeks, 6 weeks, 8 weeks, 10 weeks, and 12 week after enrollment. Sessions are co-lead by a nurse and a PED.
3) Six brief telephone sessions (approximately 10-20 minutes) implemented after the conclusion of the 5 TEAM group sessions. Calls will be conducted every 2 weeks for 12 weeks, and made in alternating order by the nurse and the peer educator. Calls will reinforce group session content, provide social support and facilitate linkage with other care providers. Each nurse will make 3 calls and each peer educator will make 3 calls. The RCT will use the same forms and data collection materials for calls as in the NINR pilot.

Tailoring to meet the unique needs of AA men: Recognizing expected heterogeneity within the enrolled sample, we will customize content to meet personalized needs. The main expected foci for alternative approaches are age, care partner availability and time since stroke. TEAM groups will be matched to the greatest extent possible by age (< age 65 vs. > age 65, when Medicare benefits typically begin), care partner status (yes/no) and time post-stroke (≤ 1 year vs. > 1 year). In addition, to reduce the burden on care partners and to accommodate men without care partners, TEAM content that focuses on care partner effort will offer alternative approaches (for example, community resources and supports).

TEAM Interventionists: The investigators will hire up to 6 PEDs recruited from selected clinical practices of the co-investigators and train them using procedures similar to the TEAM pilots. If necessary, interventionist training

can be conducted remotely. Training sessions will be video recorded for use in future trainings. TEAM will be implemented in outpatient locations that are convenient to public transportation and parking. To help facilitate tailoring based on patient age, we expect to enroll at least 2 younger (< age 65) peer educators and will assign the younger peer educators to lead the younger-age TEAM groups.

TEAM Curriculum: Topic content is noted below. In the RCT, content is delivered in 5 sessions.
Session 1: Orientation and introductions, emphasize ground rules, establish a therapeutic relationship, facts and myths about stroke, overview and interactive discussion of stroke risk factors
Session 2: Medications to manage complications and reduce future risk, nutrition for physical and emotional health, effects of exercise, smoking and other substances in recovery
Session 3: Making healthy changes, problem-solving skills and the IDEA approach (**I**dentify the problem, **D**efine possible solutions, **E**valuate the solutions, **A**ct on the best solution)
Session 4: Talking with health care providers, making the most of your clinical team, coping with stress and depression, personal care plan to take care of the body and mind.
Session 5: Medication routines, acknowledgement of group progress, self-management and recovery as a lifestyle.
Fidelity to TEAM will be evaluated by non-interventionist study staff randomly attending 20% of sessions using a standardized check-list to determine if sessions covered relevant TEAM processes, content, and format as appropriate.

Wait-list control. Individuals randomized to WL control will participate in their regular medical care for a period of 6 months, after which they will then receive the TEAM intervention as a supplement to their regular medical care.

Sharing of Results with Research Participants
Although there are not specific plans to share results with participants or their doctors, the lab results will be recorded in the participant's UH Electronic Health Record so their physician will be able to view it if they are part of the UH system. Likewise, if participants receive their care as part of the UH system and have access to their electronic health record, they will also be able to view their lab results there. Should a participant or their provider request a copy of the lab results we will give the participant a copy or send a copy to their provider after the participant has signed a release of information form.

Study Personnel:
The study PIs will oversee and be responsible for all aspects of the study including study regulatory matters, human subjects requirements, study implementation, study staff supervision, and data collection, analysis and reporting.

Risks to Research Participants
Participants will not be compelled to participate in any way in the activities of the project. Participants will also be free to withdraw from the study at any time without penalty. This study involves completing a set of self-report instruments, along with qualitative interviews. All instruments have been utilized in outpatient research settings and are not associated with risks to patients. The behavioral intervention intended to enhance post-stroke risk reduction is not generally known to increase risk to individuals. Because of the nature of group interaction, patient confidentiality cannot be guaranteed however, the importance of respecting other group members' privacy will be stressed to all subjects. The risks to the subjects will be primarily those of talking about some matters that they may find uncomfortable. Participants consented prior to August 1, 2024 will have blood drawn three time (about a tablespoon each time) over a 12-month period, and those consented on or after August 1, 2024 will have blood drawn 2 times over a 9 month period. There is minimal risk to blood draw. In addition, we do not anticipate this study causing any adverse events; however, should an adverse event occur, we will report it to the IRB. In addition, we will have a Safety Monitoring Committee (SMC) that will assess safety annually and as needed to ensure the evidence-based clinic-level intervention does not cause any increased harms.to minimize burden or distress.

If at any point a subject presents with what are deemed to be unsafe blood pressure readings of a systolic blood pressure of ≥ 170mg Hg or a diastolic blood pressure of ≥ 120 mm Hg, the study PIs or the stroke neurologist

investigator will be notified. The study staff will notify the subject's clinician. In the event that any participants experience an emergent change in medical state or the subject's clinician deems it necessary, the individual will be referred to the closest emergency department.

Likewise, if during the course of the assessments or intervention sessions, the subject communicates to the rater, nurse educator, PED, or investigator that the subject may be in immediate danger or at acute risk of harm to self or others, (for example, reporting a suicide plan), the study staff interacting with the individual will immediately notify 1) The study PI and/or 2) The patient's clinician so that all available and appropriate measures may be taken to ensure the prompt safety and most appropriate care setting for the patient. Additionally, the intervention manual will list local and nationally available resources for the treatment of alcohol, drug, and nicotine abuse/addiction and mental health treatment.

Provisions to Protect the Privacy Interests of Research Participants
Complete confidentiality cannot be assured due to the nature of group interactions. Participants in the TEAM intervention will be requested to maintain other participants' confidentiality. Confidentiality of research data will be protected in several ways. Patient identifiers at the analytic level will not be the same as the patient's clinical medical record number. The files that link the patient identifiers to the study numbers will be kept in locked cabinets in the PIs office. Only aggregate data will be presented or published and will be presented such that individual patients cannot be identified. The proposed project's research personnel who will have access to subject identities are the study PI, co-investigators, and the study research assistants. All study personnel will be required to be certified in the protection of human subjects throughout the study.

The recruitment barriers survey will be anonymous and will not collect any identifying information from respondents.

Potential Benefit to Research Participants
There may be several potential benefits to the participants. Subjects being interviewed may find it helpful to discuss their experience with stroke or TIA. TEAM intervention participants (N=80) will be provided with one individual and 5 group education/support sessions as well as telephone follow-up immediately after randomization while the WL participants will be provided with one individual and 5 group education/support sessions as well as telephone follow-up that begins 6 months after randomization . Some participants may benefit from participation in the sessions (e.g., improved health, improved understanding of stroke risk factors, and understanding of the importance of and develop better skill at self-care behaviors) and some may find it helpful to talk about their conditions. Individuals will all receive standard clinical care in addition to TEAM or to WL.
There is no guarantee of benefits to any participants. However, it is the goal of this project to contribute to self-management, which can be useful in improving stroke risk-reduction and prevent recurrent stroke. It will be explained to participants that their participation in the study may not benefit them in any way but may be of benefit to other patients in the future.

Withdrawal of Research Participants
Individuals will be discontinued from the protocol prior to 12 months (or 9 months where applicable) if they wish to withdraw for any reason at any time. Since the intervention is an addition to their regular treatment and does not include medication, there is no need for follow-up with the research team.

Should the need arise to discontinue a patient from the study because of symptom worsening or for any other reason, we will collaborate with their non-study related clinician to determine treatment options for that patient following study discontinuation.

Alternatives to Participation
The alternative is for research subjects not to participate.

Costs to Research Participants
There are no costs to research participants or their insurance companies. All expenses, including blood draws are covered by the grant.

Research Participant Compensation
Participants consented before August 1, 2024 will be compensated $50 for completing the first 5 assessment visits and $100 for the final assessment (a total of $350 if they complete screening plus all five assessment points). Participants consented on or after August 1, 2024 will be compensated $50 for completing the first 4 assessment visits and $100 for the final assessment (a total of $300 if they complete screening plus all four assessment points). Participants and care partners who participate in the qualitative interview portion will be compensated $50 for each qualitative interview.

Participants and care partners will also receive assistance with transportation in the form of a bus pass or a parking pass

Peer Educator Dyads will receive $40 per study activity (i.e., training session, intervention session, meeting with PIs, qualitative interview, etc.) with the exception of the one-on-one calls for each cohort, for which they will be paid $60 for each round of calls to all participants after the 5 TEAM group sessions.

All study payments will be made in the form of a check, reloadable debit card, gift card or direct deposit. Cash payments will be available for participants if they find that cashing a check or using a debit card or gift card is burdensome.

Throughout the course of the TEAM intervention sessions, small items of insignificant value (e.g., $5 gift card, pens, notebooks, key tags, lanyards, mini calendars, etc.) may be given and will not be used as a contingency for study participation. We may also send participants greetings cards (e.g., birthday, holiday, etc.) while they are in the study.

Participants in the recruitment barriers survey will not receive any compensation for completing the survey.

Provisions to Monitor the Data to Ensure the Safety of Research Participants
The data plan identifies the Principal Investigators of the NIH grant, Drs. Martha Sajatovic and Carolyn Still as the primary monitors of risks to human subjects. Serious adverse events will be reported (as described below) to a Safety Monitoring Committee (SMC), the IRB, and project officer of the funding source.

The Safety Monitoring Committee (SMC) will be composed of 2 individuals who are independent of the protocol: Svetlana Pundik MD, who is experienced in stroke care/stroke risk and Farren Briggs PhD, who has expertise in biostatistics/population health. Annually throughout the project, this committee will review data on all ongoing studies regarding (1) all causes of mortality and (2) morbidity (hospitalizations, ER visits, and injuries/problems). Additionally, the rate of recruitment refusal (percent and reasons) and subject attrition (percent and reasons) will be tracked and reported at these reviews. Differential attrition from the experimental groups also will be monitored. If concerns or problems are identified by the SMC they will be reported to the IRB and NIH. Study protocols for human subjects monitoring and protection of risks and protection of confidential participant data will be reviewed by the SMC at the onset of each new study. In addition, the SMC will provide ad-hoc external review and guidance should there be safety concerns or significant events that occur between the annual reporting time-points.

The adverse events tracking will be prepared as a report to the SMC and shared as appropriate with the IRB of record and the NINR (via Project Officer) by the Principal Investigators.
Specifically, the following will be reported, in writing:

- Adverse events that are Unanticipated Problems and are (1) related to participation in the research, and (2) places the subject at greater risk of harm than listed on informed consent will be reported to both the IRB and NINR (via Project Officer) within 14 calendar days of discovery of the problem or event.
- Unanticipated problems that are serious adverse events (e.g., death, a life threatening experience, inpatient hospitalization or prolongation of existing hospitalization) will be reported to the IRB and NINR (via Project Officer) within 7 days of discovery of the problem or event.
- Unanticipated problems that are non-serious and expected adverse events will be reported annually at continuing review to the IRB and annually to NINR (via Project Officer).

Data Analysis Plan
Quantitative Data Analysis:

Verification of Data Accuracy: Preliminary steps will include examining the frequencies of items to identify the range of variability of each item (e.g., having a range of responses and not having any one category account for >90% of all possible category responses), determine coding inaccuracies, check for outliers, and missing data, and to verify sample size, and normality of data. Descriptive statistics will include examining means, standard deviations, and testing for normality using skewness and kurtosis. Prior to testing the Aims, additional correlational analyses will be run as the first step to identifying potential relationships among components. These correlations will be used to prescreen potential violations of the assumptions of correlation. Additionally, scatter plots between the two variables can help identify influential cases, as well as patterns of nonlinearity and non-constant error variance that may reduce Pearson's *r*. To remedy the potential violation of the assumptions, influential cases can be removed and models retested to determine Pearson's *r* improvement. Data transformations can be used to correct issues concerning non-linearity, non-constant error variance, and non-normal error variance. These pre-screening techniques will help prevent potential problems that may occur when these relationships are tested in the path analysis.

Repeated Measure Analysis of Variance for Aim 1: The underlying analyses for Aim 1 are built around the repeated measures analysis of variance (RMANOVA) to test mean differences in systolic BP and HDL over 6 months. The primary analysis will compare groups (TEAM vs. WL control) at 6 months (2 group X 3 time points RMANOVA) with additional follow-up from 6 to 12 months (or 9 months where applicable) to assess sustainability of the TEAM intervention (2 group X 5 time points RMANOVA). When using a repeated measures ANOVA, it not only assesses mean differences across time, but also assesses group differences, as well as, the interaction of time X group which will allow us to test the trend of the means over time between the 2 groups. The RMANOVA, not only can be used to determine if there are mean differences over 6 months, it can also use orthogonal polynomial contrasts to determine linear and quadratic trends of the means across time. To identify the shape of the trend in the means for sustainability of the TEAM intervention, orthogonal polynomials, weights assigned to each time period will be used to model linear or quadratic (non-linear) shapes of these trends. RMANOVA can determine if these trends in means are significant and can also evaluate change over time. A linear trend is indicated if there is a steady increase or decline in scores from the baseline to the fifth time wave (12-months), or 4th wave (9 months) where appliable. A quadratic trend is indicated if there is a change in direction based on scores across the time waves. For example, if there is an increase in mean scores from baseline to the subsequent time waves, but a decline in scores at the final time waves, this would be indicative of an inverse U trend for the 5 time points and a return towards the mean score from baseline to the final time waves.

The major assumption to be tested with RMANOVA is sphericity. Sphericity is a form of compound symmetry and refers to the equality of variances of the differences between each time wave.[142] If the assumption of sphericity is violated based on the Mauchly's test, SPSS provides an adjusted F, df, and p-value in repeated measures ANOVA to account for this violation. Repeated Measures Mixed Models approaches will also be examined as an alternative analysis.

Autoregressive Model for Aim 2: Aim 2 examines the extent to which the self-management process and behavioral outcomes mediate how the TEAM intervention impacts primary and secondary outcomes (systolic BP, diastolic BP, serum lipids, HbA1c) over 12 months (or 9 months where applicable). In the proposed study we intend to use an autoregressive (AR) contemporaneous model to gain a better understanding of how the self-management process impacts behavioral outcomes, which in turn allows us to test how behavioral outcomes impacts primary and secondary health outcomes across 5 time waves over a year.

AR models are used to assess longitudinal data over time. The term "autoregressive" refers to the process of regressing the measure at one-time point on its previous time point value. Variables measured at earlier time points than the immediate previous time point have no direct impact on the current measure. A benefit of AR models is the ability to combine multiple univariate AR models into a multivariate AR model. These models allow for both autoregressive and contemporaneous coefficients. Contemporaneous effects test the strength of

prediction of one variable on an outcome variable within a time wave controlling for the outcome variable's previous time score identified in the univariate AR component of the model. For example, the contemporaneous effects of self-management process at Week 12 on behavioral outcomes (e.g. path marked A1) while controlling for the influence of behavioral outcomes at Baseline (e.g., path 1) will be examined. Paths marked A1 and A represent the contemporaneous effects of the self-management process on behavioral outcomes immune across the 5 time waves. Paths marked B represent the contemporaneous effects of behavioral outcomes on primary and secondary outcomes across the 5 time waves.

Autoregressive model while controlling for contextual variables to examine secondary aims: For the secondary aims, autoregressive models will be used to assess TEAM and WL's impact on the primary and secondary health outcomes while controlling for contextual variables such as age, personal and neighborhood stress, discrimination, depression, anxiety, social roles, health-condition related factors, health literacy and care partner variables. We will use the AR models developed for Aim 2 and add the contextual variables as a set of covariates predicting the AR model. This will allow us to determine if the contextual variables influence primary and secondary outcomes over time.

Some individuals may drop out of the study or not participate at a specific wave. In these cases, individuals will have incomplete data. AMOS allows for analysis of incomplete data using FIML estimation. Specifically, issues of nonrandom missing data are of particular interest in longitudinal data because dropout rates are not a random process and to the extent this is predicted by variables included in the data analysis FIML will provide unbiased parametric estimates.

Recruitment Barriers Categorization
Using a group consensus process, the study team will discuss the summative list of barriers, grouping them into environmental/social (macro), healthcare system/public services (mediator) and individual -level barriers.

Sample size calculations: The NINR-funded TEAM pilot demonstrated significant group differences compared to TAU for mean systolic BP at 6 months ($p = 0.03$). For a sample size of 38 this would be equivalent to a large effect size of .90. Covariates included in the respective ANCOVA models were baseline systolic BP, age, diabetes status, and BMI. At 6 months, an unadjusted mean difference of 15.4 was observed, with TEAM having a lower systolic BP mean than TAU. Our pilot work suggested an attrition rate of 26.3 %, but we will conservatively assume 30% attrition at 6 months in the proposed project. For a 2 group RMANOVA testing between group differences, Type I error of 0.05, we will have power of 0.8 for a moderate to small effect size of 0.21.

Qualitative Data Analysis:
We will use a directed content analysis approach to analyze the transcripts of the interviews.[153] The initial codes will be derived from topical areas of the interview guides and subsequently clustered into categories to generate constructs (themes) and elaborate the relationship among constructs.[148, 154] A coding dictionary will be constructed that includes mutually exclusive code definitions. The coding structure will be reviewed after a preliminary analysis of a sub sample of transcripts, and the dictionary will be refined through comparison, categorization and discussion of each code's properties and dimensions.[155] At least two research team members will independently and collaboratively code each transcript. Inter-rater reliability will be assessed using the Kappa Statistic,[148] and the qualitative team (Drs. Killion, Sajatovic and Still) will discuss/ resolve any discrepancies Refined codes will then be applied, with coding decisions recorded using ATLAS. Significant themes, derived from the respondents' statements, will enable identification/characterization of perceived barriers and facilitators. After the analysis is completed, a minimum of five men from TEAM and 5 men from WL will review the identified themes and related excerpts to help discern the validity of our interpretation.

Table 1: Schedule of study procedures

		Screen	BL	3 M	6 M	9 M	12 M**
Estimated time requirement of visit		**60 min**	**90 min**	**60 min**	**90 min**	**60 min**	**90 min**
Screening, Informed consent	**Measure**	**X**					
Screening measures 1. Functional status post-stroke 2. Confirmation that person had stroke or TIA	1. Barthel score 2. ABCD Scale	**X**					
Demographics	Demographic variables such as age, gender, race, ethnicity, education, income, etc.	**X**					
Primary Health Outcome: Systolic BP	Systolic BP		**X**	**X**	**X**	**X**	**X**
Secondary Health Outcomes: Biological risk markers*	1. diastolic BP 2. cholesterol 3. HDL, LDL 4. triglycerides 5. HbA1c 6. BMI		**X**		**X**		**X**
Contextual factors: 1. Perceived stress. 2. Neighborhood stress, 3. Perceived health status (physical function, anxiety, depression, social role, sleep, fatigue, pain) 4. Discrimination 5. Medical burden, 6. CVD risk 7. Health literacy 8. Care partner variables	1. Perceived Stress Scale 2. Northeast Ohio Community and Neighborhood Data for Organizing (NEOCANDO) 3. Patient-Reported Outcomes Measurement-29 4. Everyday Discrimination Scale (EDS) 5. Self Rated Charlson Comorbidity Index Cardiovascular index-(CVHI)/Pilkerton CVHI (all except food questions) 6. Rapid Estimate of Adult Literacy in Medicine short form (REALM-SF)		**X**	**X**	**X**	**X**	**X**
Self-management processes: 1. Stroke knowledge 2. Self-efficacy 3. Social support	1. Set of Stroke Knowledge Questions 2. General Self-Efficacy Scale 3. Medical Outcomes Study Social Support Survey (MOS-SS)		**X**	**X**	**X**	**X**	**X**
Proximal behavioral outcomes: 1. medication-taking 2. treatment adherence 3. diet 4. exercise 5. smoking 6. Alcohol 7. substance use	1. stroke risk-reduction drugs pt is taking 2. Tablets Routine Questionnaire (TRQ) 3. Nutrition Data System for Research (NDSR)* 4. Morgenstern Physical Activity Questionnaire 5. Fagerstrom Test for Nicotine Dependence 6. National Institute on Drug Abuse (NIDA)-Modified Alcohol, Smoking, and Substance Involvement Screening (ASSIST)		**X**	**X**	**X**	**X**	**X**
Randomization			**X**				
TEAM implementation in the experimental arm			→				

TEAM implementation in the waitlist arm						→	
Participant satisfaction	Satisfaction evaluation				**X**		
Qualitative Assessment (for PEDs and subgroup of participants)			**X**		**X**		

* The NDSR will be completed only at BL, M6, and M12

**Those randomized on or after August 1, 2024 will not be assessed at 12 months

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