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STUDY PROTOCOL

The Targeted Management (TEAM) Intervention for Reducing Stroke Risk in African American Men: Rationale and Study Design of a Prospective Randomized Controlled Trial

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Background: African American (AA) male survivors of strokes or transient ischemic attacks (TIA) have the highest risk of recurrent stroke when compared to other racial-ethnic men. However, there is a paucity of evidence-based strategies, including organizational, educational, or behavioral interventions, that targets secondary stroke risk reduction in AA men.

Methods: Targeted Management for Reducing Stroke Risk (TEAM) is an ongoing, 6-month prospective, randomized controlled trial that will determine whether a curriculum-guided self-management approach, using peer dyads (men who had a stroke or TIA and their care partners) will improve post-stroke care in AA men.

Results: The study sample will consist of 160 AA men who have experienced a stroke or TIA within 5 years, randomized to TEAM or Wait-list control group. The primary outcome changes in systolic blood pressure (BP) and high-density lipoprotein (HDL), while secondary outcomes include diastolic BP, total cholesterol, low-density lipoprotein, triglycerides, and glycemic control for diabetics. We hypothesize that AA men in TEAM will have significantly lower systolic BP and higher HDL when compared to AA men in the Wait-list control group at 6-month.

Conclusion: Persistent disparities for stroke burden in AA men highlight the need for novel interventions to promote secondary stroke-risk reduction. Building on promising pilot data, TEAM uses a group format, with a nurse and patient co-led intervention focused on AA men and family needs, practice in problem-solving, and attention to emotional and role management. In addition, the TEAM approach may help reduce stroke risk factors and health disparities in AA men.

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Keywords: stroke, transient ischemic attack, stroke prevention, African-Americans, health disparities

Introduction

Stroke is the fifth leading cause of death in the United States.[1] While stroke mortality has declined over the last decade, African Americans (AA) are twice as likely to suffer from a stroke at a younger age (<44 years old) and have higher mortality rates when compared to other racial-ethnic groups.[1,2] In 2016, nearly 800,000 Americans had a stroke, costing the US healthcare system $34 billion dollars.[2,3] National vital statistics show the age-adjusted death rate for stroke is

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markedly higher in AA men when compared to the overall US population (56.7 versus 37.3 per 100,000), including women.[2,3]

AA stroke mortality and incidence are partially explained by disparities in their stroke risk profiles and are particularly high among AA men.[4,5] Racial differences in prevalence, awareness, treatment, and control of stroke risk factors, such as hypertension, hyperlipidemia, obesity, and diabetes largely contribute to the higher adverse events and stroke incidence in AA men.[2,6–8] Evidence also suggests that social determinants of health, stress, and cultural factors all play a role in stroke disparities and health outcomes.[4,8,9] Moreover, race-specific inequalities (eg, discrimination, stigmatization, and microaggression) trigger individual pathophysiological changes to the body that contribute to the disproportionate burden of stroke in AA men.[10,11] These problems subsequently result in stress or the inability to cope with adversity and lead individuals to adopt unhealthy behaviors such as smoking, poor nutrition, or physical inactivity. Notably, all of these factors can potentially increase the risk of a mini-stroke (transient ischemic attack [TIA]), a precursor to a stroke, occurring before 12% of all strokes.[1,2]

More importantly, not only is the burden of first-time stroke higher in AA, the risk of recurrent stroke is higher in AA when compared to non-AA.[12] Recurrent stroke risk increases over time and 25% of stroke survivors will die of a recurrent stroke.[13,14] A recent analysis of a global, multicenter clinical trial focused on stroke and cardiovascular event recurrence evaluated 3,470 (20% AA) recent stroke patients (aged 35 years or older) and followed them for 2 years.[15] AA patients (enrolled in the US and United Kingdom) with a recent stroke had approximately 60% higher risk of recurrent stroke compared to their white counterparts.[15] This difference was explained by a substantially greater vascular risk factor burden in the AA.[15] Furthermore, these results suggest that targeted care for better risk factor control after a stroke in AA may help close the disparity gap in racial stroke outcomes.[16]

Prevention of Secondary Stroke to Improve Post-Stroke Outcomes

Evidence is growing regarding the contribution and the interplay of modifiable risk factors and the reduction of stroke mortality.[17] A statement by the American Heart Association/American Stroke Association (AHA/ASA) on the prevention of incident or recurrent stroke highlights interventions to improve post-stroke outcomes and reduce the risk for future stroke.[17] These interventions include evidence-based pharmacotherapies[18] and aggressive management of stroke risk factors, such as hypertension,[19] hyperlipidemia,[20] and diabetes.[21] In addition, recommendations for behavioral modifications, such as smoking cessation, change in diet, weight loss, exercise, and stress management, are strategies shown to reduce secondary stroke mortality.[17] However, AA men have the greatest underuse of evidence-based post-stroke care for multifactorial reasons, including low socioeconomic status, inadequate health insurance, and poor access or referral to outpatient rehabilitation.[4,22] Unfortunately, this is compounded by low AA stroke risk factor awareness that might prevent future stroke.[23] These persistent challenges highlight the need for further efforts to reduce the risk of recurrent stroke in AA.[24–28]

To improve post-stroke care, self-management interventions are recommended as a method of supporting individuals to change behavior and take an active part in managing their own health,[21,29] as well as develop skills to monitor, cope, and adapt to living post-stroke.[30,31] While there are a number of reports on self-management for stroke survivors,[16,31–34] there is a paucity of evidence-based strategies, including organizational, educational, or behavioral interventions that target secondary stroke risk reduction in AA men.[35] The Prevent Recurrence of All Inner-city Strokes through Education (PRAISE) trial developed a culturally tailored, peer-led, and community-based chronic disease self-management program to address reducing stroke risk factors among minority stroke survivors.[33] Results suggest that the PRAISE was associated with a reduction in blood pressure (BP) in individuals who had experienced stroke or TIA within the past 5 years.[34] However, the study was comprised of mostly females (60%) and did not demonstrate significant improvements in other health indicators (eg, low-density lipoprotein [LDL], use of antithrombic medication). Importantly, among factors contributing to stroke risk disparities in AA, systolic BP is a critical modifiable risk factor that accounts for half of the combined Framingham risk factor effect.[8] Thus, approaches that target systolic BP in AA men and other health indicators (Lipids, cholesterol, hemoglobin A1C) may help reduce stroke risk factors and have the potential to close the stroke disparity gap in AA men.

Integrating Targeted Management for Stroke Risk Reduction

Targeted Management (TEAM) is a novel intervention, developed by this study team,[36] to promote secondary stroke-risk reduction in AA men at high-risk for recurrent stroke. TEAM uses a group format, with a nurse and patient co-led intervention focused on patient and family needs, practice in problem-solving, and attention to emotional and role management in stroke risk reduction. Preliminary work testing the feasibility, acceptability, and efficacy of TEAM (versus treatment as usual [TAU]) in AA men within 1-year of experiencing a stroke or TIA demonstrated improvements in mean systolic BP, high-density lipoprotein cholesterol (HDL), and glycosylated hemoglobin (HbA1c) at 24 weeks among AA men receiving the TEAM intervention.

TEAM aligns with the Individual and Self-Management Theory (ISMT) of Ryan and Sawin[37] and combines self-management training, peer support and behavioral modeling within a family framework that emphasizes the involvement and engagement of the family, acknowledges the presence and variability of family/support network stress, and is culturally sensitive to the needs of AA men. Given the lack of post-stroke risk reduction approaches specifically targeting AA men, TEAM has the potential to advance care and reduce stroke risk in this vulnerable population.

Purpose

This paper describes the design and methods of a 6-month prospective, randomized controlled trial (RCT) to examine the effects of TEAM versus a Wait-list control group on systolic BP and HDL in AA men with stroke or TIA. We hypothesize that AA men in TEAM will have significantly lower systolic BP and higher HDL levels when compared to AA men in the Wait-list control group at 6-month follow-up.

Methods and Materials

Study Design

The proposed project is a 6-month prospective RCT comparing the TEAM intervention and Wait-list control group (Figure 1). This research protocol was approved by University Hospitals Cleveland Medical Center's (UHCMC) Institutional Review Board and will be conducted in accordance with this trial will be conducted in accordance with the Declaration of Helsinki. All study participants will provide written informed consent prior to study enrollment.

To optimize study 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 RCT evaluation and from 6 to 12 months post-baseline to evaluate the sustainability of the TEAM intervention. Individuals in the Wait-list control group will receive the TEAM intervention for a 6-month period after a delay, starting at month 6 and concluding at month 12 (post-baseline). The primary health outcome (Aim 1) is a change in systolic BP, while secondary health outcomes (Aim 2) include a change in other biologic parameters of stroke risk—diastolic BP, low-density lipoprotein (LDL), HDL, triglycerides, and glycemic control (HbA1c) for diabetics. Other goals of this study include exploring how contextual factors (age, individual and neighborhood stress, racial discrimination, perceived health, depression, anxiety, social role, health literacy, CVD-related factors), process factors (stroke knowledge, self-efficacy, perceived social support), and proximal health behaviors (diet, exercise, smoking, and tobacco/substance use) may impact the primary and secondary health outcomes. Qualitative assessment will evaluate TEAM and Wait-list control group from both the perspective of AA men and their care partners (someone who is involved in their stroke recovery care or support network).

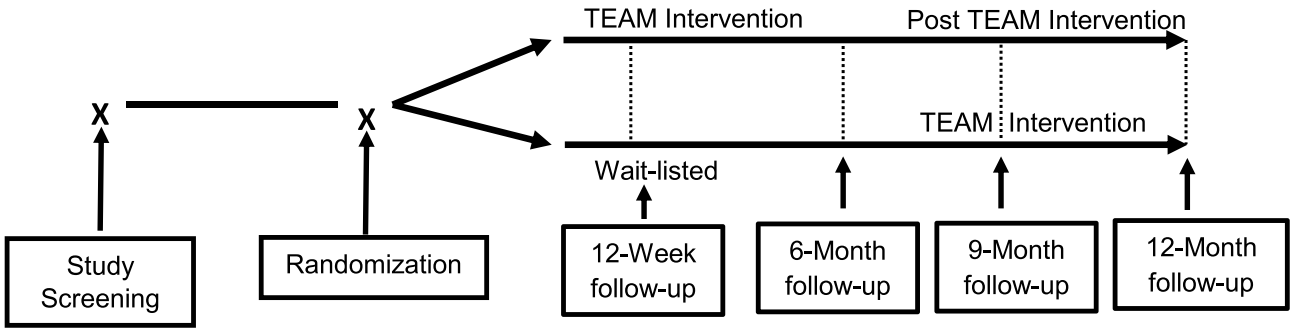

Figure 1 Randomized control trial study design.

Participants

The study sample will consist of approximately 160 AA men who have experienced a stroke or TIA and are within 5 years of a hospital discharge from an acute stroke program or Emergency Department visit for TIA. TIA categorization will be based upon the ABCD TIA score,[38–40] a statistically and clinically valid method of identifying individuals with TIA. Eligible participants will be enrolled if they meet the following inclusion criteria: 1) self-identified as AA male, 2) current Barthel Index (BI) score of >60 (indicating no more than mild-moderate stroke-related functional deficit),[41,42] and 3) able to participate in groups. Participants will be excluded if they are unwilling or unable to provide informed consent or if their stroke was felt to be related to sickle-cell disease. Involvement of care partners will be encouraged but not a requirement for this study.

The sample size for this study was determined based on the authors' previous pilot work,[36] which demonstrated significant group differences on the primary outcome systolic BP at 6 months ($p = 0.03$). Moreover, power analysis was calculated for RMANOVA, testing between-group differences (TEAM and Wait-list control) would achieve adequate power with a sample size of 38 for each group. Allowing for a conservative 30% dropout, using an alpha of 0.05, a moderate to small effect size of 0.21, and power of 0.80 indicates a final sample of 160 ($n = 80$ in each group) will be sufficient to detect differences between the study groups.

Setting

This study will take place in Cleveland, OH—a large metropolitan city in the Midwest, where the population is approximately 384,000 people, the median age is 36, and the median household income is $28,000. AA makes up 50% of the study site population and 25% live below the federal poverty level.[43]

Recruitment

Participants will be recruited from two large academic medical centers in Northeast Ohio. Methods for identifying potentially eligible participants within the clinical practice of the research settings will include a targeted review of medical records or databases for those meeting the trial's inclusion criteria, Institutional Review Board (IRB)-approved posted advertisements, direct mailings, and referrals from providers/employees within the practice and/or from practice participants themselves.

Treatment Randomization

After informed consent, and screening and baseline procedures, individuals will be randomized on a 1:1 basis to either TEAM ($n = 80$) or Wait-listed control ($n = 80$). Block randomization with block sizes ranging randomly between 4 and 8 consecutive patients will be employed to ensure that equal numbers of TEAM and Wait-list control participants occur within strata and are balanced with respect to relevant comorbidities (diabetes and previous stroke). The randomization list will be computer-generated by biostatisticians who are not members of the study staff.

Intervention

TEAM Intervention Arm

We have developed a curriculum-guided self-management approach that promotes self-management training, peer support, and behavioral modeling to reduce stroke risk in AA men post-stroke/TIA.[6,44] The TEAM intervention (Figure 2) consists of individual and group sessions, as well as telephone follow-up sessions. TEAM sessions are delivered by a nurse educator and a peer dyad. The Peer Dyad (or PED) consists of an AA male who has experience in managing his own stroke risk and his care partner. The steps of the interventions are described next.

First, there is a single individual session with the participant, his care partner (if applicable), the nurse educator and a PED. The initial session covers introductions, orientation, and logistic planning and takes place within 30 days of study enrollment and prior to the first TEAM group session. Next, participants will complete five interactive group sessions. Each group session will include 6–10 AA men with their care partner and occur every 2 weeks beginning at 4 weeks. Sessions are co-led by a nurse and a PED and will last approximately 60 minutes. Following the group-session series, participants in TEAM will have six telephone maintenance sessions, spaced approximately every 2 weeks with the nurse educators or a member of the PED in an alternating fashion. Phone sessions will reinforce content from the group sessions, serve as a behavioral mode, and provide social support.

Wait-List Control Arm

Individuals randomized to the Wait-list control group will participate in their regular medical care for 6 months.

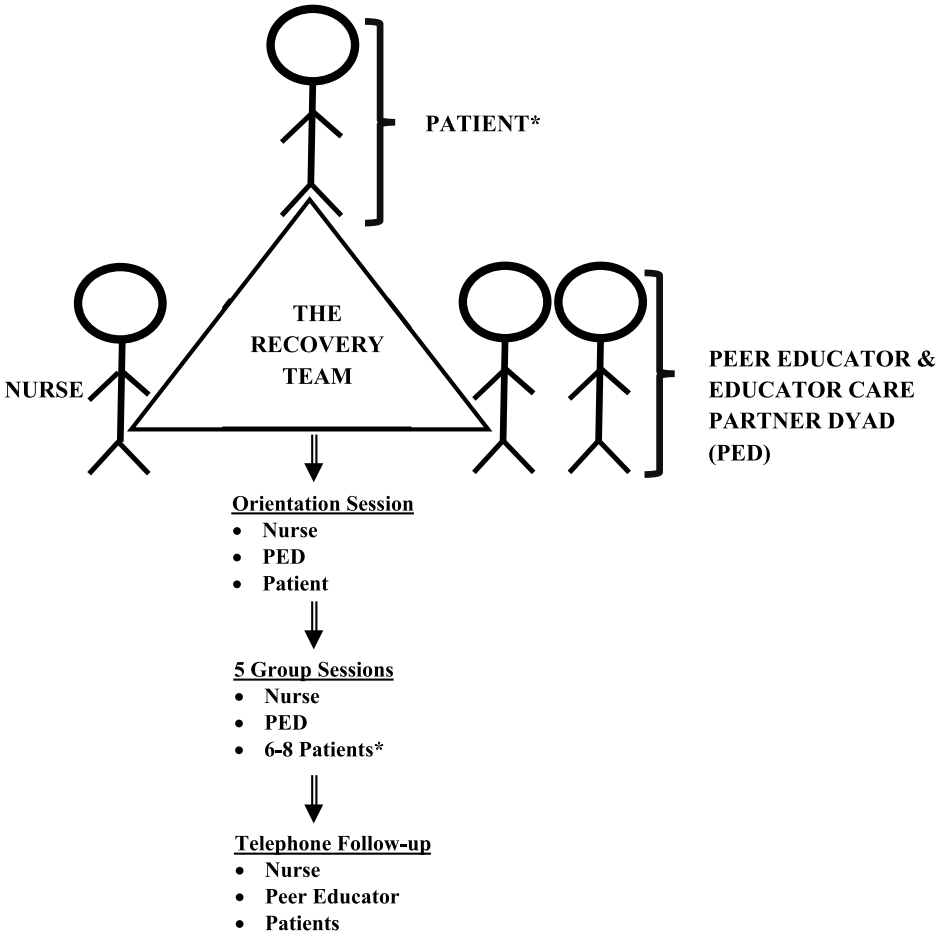

Figure 2 TEAM participants and encounters. *Patient care partner also encouraged to participate if available.

After 6 months, the Wait-list group will receive the TEAM intervention as a supplement to their regular medical care for 6 months.

Procedures

After screening and enrollment, each research participant (in both groups) will be assessed at baseline, 3, 6, 9, and 12 months. Data will be obtained from patient interviews, BP evaluation, and laboratory testing (collected at baseline, 6 and 12 months). Laboratory testing will be conducted only will be collected by registered nurses on the clinical research unit. Trained research assistants will conduct study visits, while registered nurses on a clinical research unit will collect BP and laboratory data. 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.

Measures

Baseline assessment will include self-reported demographic information as well as contextual, process, behavioral and health outcome factors relevant to the ISMT theoretical model. Study measures are described below. All data will be collected and managed in electronic data, REDCap (Research Electronic Data Capture).

Primary and Secondary Health Outcomes

The primary health outcome is a change in systolic BP from baseline to 6-month follow-up between TEAM vs Wait-list control participants. BP assessments will be conducted using standardized accepted procedures (appropriate cuff size, proper positioning, after 5 minutes of rest),[45,46] and based on the current 2017 American College of Cardiology/American Heart Association (ACC/AHA) blood pressure guidelines.[19] Additional biological markers indicative of stroke risk will be collected, including diastolic BP, body mass index (BMI), and

blood specimens (total cholesterol, HDL, LDL, triglycerides, HbA1c).

Contextual Factors

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 were considered. Individual perceived stress will be evaluated with Cohen's Perceived Stress Scale (PSS; α = 0.78),[47,48] a 10-item global health instrument that has been validated in the USA Neighborhood stress will be characterized using the residential neighborhood codes used by the regional Northeast Ohio Community and Neighborhood Data for Organizing (NEOCANDO) project (http://neocando.case.edu). The Patient Rated Outcomes Measurement Information System (PROMIS; α = 0.91 to 0.98) is a 29-item comprehensive self-rated measure that will be used to evaluate the perceived health status of one's physical function, anxiety, depression, social role, sleep, fatigue and pain.[49,50] Perceived racial discrimination will be assessed with the 9-item Everyday Discrimination Scale (EDS) developed by Williams and colleagues.[51] A recent systematic literature review on studies that evaluated the links between racial discrimination and hypertension noted that the EDS was one of the most widely used instruments on this topic.[52] Health literacy will be measured by the Rapid Estimate of Adult Literacy in Medicine short form (α = 0.95).[53] Physical health contextual factors will include medical burden[18,54] measured by the Cardiovascular Health Index.[55] To evaluate the patient/care partner relationship the Mutuality Scale, a 15-item instrument, will be used to assess their relationship in terms of love, shared pleasurable activities, common values, and reciprocity.[56]

Self-Management Processes

Stroke knowledge will be measured with the Stroke Knowledge Test (α = 0.65),[57,58] to examine knowledge of keystroke risk factors and stroke prevention practices. Self-efficacy will be measured with the General Self-Efficacy Scale (α = 0.76–0.90).[59,60] Social support will be measured with the Medical Outcomes Study Social Support Survey (α = 0.91).[61,62]

Proximal Behavioral Outcomes

Health behaviors known to be important to stroke risk reduction-adherence with medication, healthy diet, exercise and avoidance of alcohol and recreational drugs will be assessed. Medication-taking will be assessed in two 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.[58] The Nutrition Data System for Research will be used to evaluate diet within the past 3 days.[63,64] Exercise will be assessed with the Morgenstern Physical Activity Questionnaire (α = 0.87).[65] Smoking will be assessed with the Fagerström Test for Nicotine Dependence,[66,67] while the use of alcohol and other recreational drugs will be assessed with the National Institute on Drug Abuse-Modified Alcohol, Smoking, and Substance Involvement Screening (α = 0.77)[68,69] for adults.

Qualitative Interviews

In-depth interviews will be conducted by trained research assisted with 40 patients at baseline (half from TEAM and half from Wait-list control) to explore the perceptions of AA men post-stroke/TIA regarding barriers/facilitators, coping with stress and chronic illness, and self-managing modifiable risk factors. Individuals who provide baseline data will be interviewed again at 6-months to further understand how they are managing their stroke risk factors and what has helped them over the past 6 months in stroke recovery. In addition, interviews will be conducted with 20 care partners (10 from TEAM and 10 from Wait-list control) at baseline and 6-month follow-up to determine what they felt were the most important and helpful factors in managing stroke risk and how it might potentially be improved in the future.

Analyses

Preliminary data analysis will include examining the frequencies of items to identify the range of variability of each item study measure. Descriptive statistics will include examining means, standard deviations, and testing for normality using skewness and kurtosis. The primary analysis will compare mean differences in systolic BP across groups (TEAM vs Wait-list control) over the initial 6 months of the study. Analyses will also compare follow-up from 6 to 12 months to assess the sustainability of the TEAM intervention using repeated-measures analysis of variance (RMANOVA).

We will examine 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, HDL, serum lipids, HbA1c) over 12 months. 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 impact primary and secondary outcomes across five time waves over a year.

Discussion

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 groups. This paper describes the design and methods of an ongoing study for reducing stroke risk in AA men.

This study builds upon promising pilot work which developed and tested a curriculum-guided self-management approach-TEAM Intervention to specifically target and reduce stroke risk factors in AA men using AA peer educators (patients who have had stroke or TIA) as part of the intervention. Data from a 6-month prospective pilot randomized controlled trial conducted by this team comparing TEAM (n = 19) vs treatment as usual (TAU, n =19) found that TEAM participants had significantly lower systolic BP after 6 months (p =0.03).[6,36] Thus, this self-management intervention, targeted to minority men at high risk for stroke may reduce recurrent stroke burden in AA men.

This study is innovative in various ways: 1) it focuses on AA males, 2) it uses peer educator dyads (PED) composed of an AA male peer educator and his care partner to help deliver the intervention in collaboration with a nurse, 3) it includes other support system individual as both educators and as recipients of support/education, 4) it uses a curriculum-driven self-management program, which has rarely been used in studies of AA men, and 5) the investigation was informed by ISMT framework,[37] a conceptual model that may help explain salient experimental elements. Taken together, the health disparities focus, use of AA men as both teachers and learners, ISMT conceptual framework, and detailed curriculum represent a new research direction with the potential to advance care for AA men to reduce stroke risk.

The information gained from this study may improve the outcomes of AA men post a stroke or TIA. Treatment and self-management among individuals who have experienced these conditions is a problem of critical public health importance. The proposed research features a person-centered, holistic intervention that takes advantage of existing strengths in AA families and communities, including peer dyads who have experienced the burden of stroke. The intervention represents a practical and generalizable 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 and stroke-related disorders.

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Author Contributions

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

Disclosure

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