

Compendium

Barbershop-Facilitated Community-to-Clinic Linkage Implementation Program: Rationale and Protocol for a Novel Program to Prevent Hypertension Among Black Men

Joseph Ravenell,^{1,2,3} Tanisha Green,¹ Milla Arabadjian,^{1,3} Antoinette Schoenthaler,¹ and Olugbenga Ogedegbe^{1,2}

¹Department of Population Health, NYU Grossman School of Medicine, New York, New York, USA;

²Department of Medicine, NYU Grossman School of Medicine, New York, New York, USA;

³Department of Foundations of Medicine, NYU Long Island School of Medicine, Mineola, New York, USA

Correspondence: Joseph Ravenell (joseph.ravenell@nyulangone.org).

Background: Black men in the United States have higher hypertension (HTN) prevalence than other groups, largely due to adverse social determinants of health, including poor healthcare access. The Community-to-Clinic Linkage Implementation Program (CLIP) is effective for HTN screening in Black-owned barbershops. However, its effect on HTN prevention among Black men is untested. Here, we describe the rationale and study protocol for the development and testing of a barbershop facilitation (BF) strategy, with trained Community Health Workers, to implement and scale CLIP for HTN prevention in Black men.

Methods: The study is part of the American Heart Association (AHA)-funded RESTORE (Addressing Social Determinants to Prevent Hypertension) Health Equity Research Network. The study is tri-phasic: (i) pre-implementation—qualitative examination of factors affecting adoption of CLIP and development of BF strategy, (ii) implementation—cluster randomized control trial to test the effectiveness of CLIP with and without BF. We will partner with 20 barbershops and enroll 420 Black men with elevated blood pressure (BP)/Stage 1 HTN (2017 ACC/AHA HTN guidelines). Outcomes include reduction in BP, rate of CLIP adoption and linkage to care, and incidence of Stage 2 HTN. The study time frame is 12 months, (iii) post-implementation—we will evaluate program sustainability (6 months post-trial conclusion) and cost-effectiveness (up to 10 years).

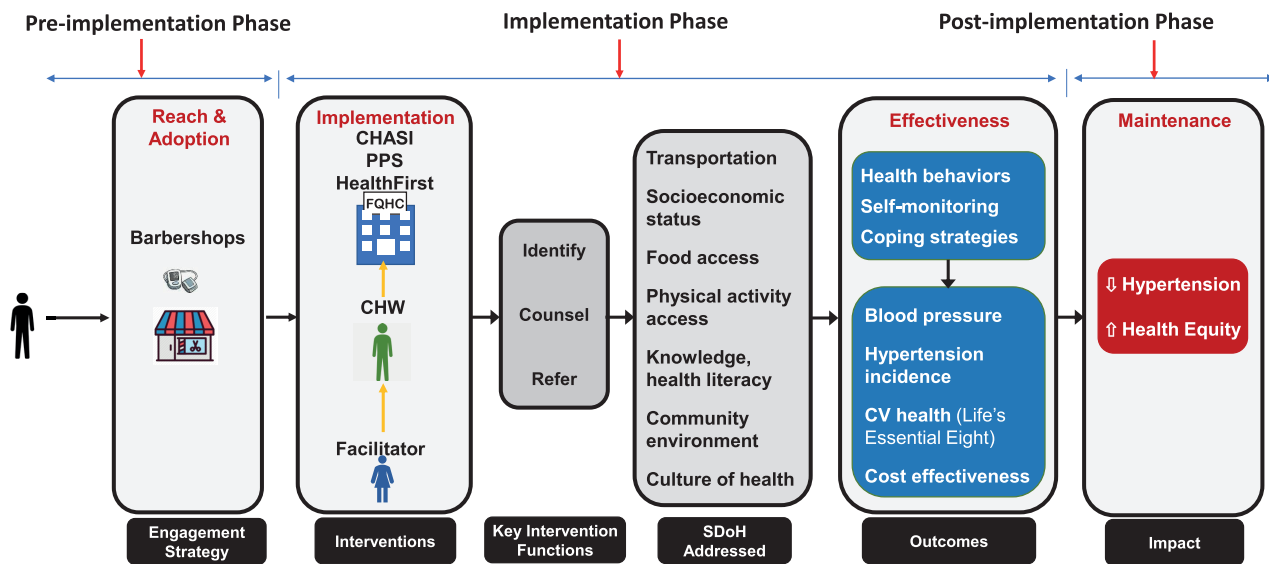
Conclusions: This study harnesses community-based resources to address HTN prevention in Black men, who are more adversely impacted by HTN than other groups. It has major policy relevance for health departments and other stakeholders to address HTN prevention in Black communities.

ClinicalTrials.gov Identifier: NCT05447962.

Keywords: Black men; blood pressure; health disparities; hypertension; implementation science; prevention

Graphical Abstract

Community-to-Clinic Linkage Implementation Program in Barbershops



CHW: Community Health Worker; CHASI: Community Health Action of Staten Island; PPS: Staten Island Performing Provider System; SDoH: social determinants of health; FQHC: federally qualified health center

Black men have the highest prevalence of hypertension (HTN) in the United States, 59%, compared to, 47% of White men.¹ Black adults have 1.8 times greater rate of fatal stroke and 1.5 times higher cardiovascular disease (CVD) mortality rate than other groups, largely due to higher HTN prevalence and uncontrolled blood pressure (BP).^{0.2,3} Adverse lifestyle behaviors (lack of physical activity, obesity, high dietary sodium intake, and low intake of fruits and vegetables), often rooted in social determinants of health, account for most of the excess HTN risk.⁴ The efficacy of lifestyle modification (e.g., weight loss, optimal nutrition, limited alcohol, and adequate physical activity) for BP reduction is well established,¹ and clinical guidelines recommend lifestyle modification for prevention and treatment of HTN. However, the implementation of lifestyle modification is suboptimal in community-based settings where most Black adults receive their care, contributing to racial disparities in HTN.¹

Social determinants of health (SDoH), defined as the environments in which people are born, grow, live, work and age, and the systems in place to deal with illness, are major drivers for the implementation of lifestyle modification.^{5,6} Adverse SDoH (e.g., food insecurity, low health literacy, neighborhood deprivation) have been associated with a higher incidence of HTN, and are pervasive in Black communities.^{7,8} In addition, medical mistrust and perceived racism in healthcare among Black men contribute to their lower engagement in health-promoting behaviors and lower use of preventive health services compared to women and other racial and ethnic groups.^{9,10} However, community-to-clinic interventions have shown promise in improving disease management and screening among underrepresented groups, particularly among those experiencing adverse SDoH.¹¹⁻¹³

In 2019, we partnered with the New York City Department of Health and Mental Hygiene (NYCDOHMH) to develop an HTN screening program using Black-owned barbershops in the Borough of Staten Island. This program, Community-to-Clinic Linkage Implementation Program in Barbershops (CLIP), is a

multilevel evidence-based intervention designed to mitigate adverse SDoH via linkage to care, health system navigation, and referral to services to address social barriers.

Community health workers' role in HTN prevention and mitigation

Community health workers (CHWs) are trained laypeople who share life experiences with people in the community and can effectively disseminate evidence-based programs between Black communities and healthcare systems.¹⁴ Studies have demonstrated that CHWs improve HTN self-management, including appointment keeping, adoption of healthy lifestyle behaviors, and medication adherence, in Black communities.^{14,15} CHWs play a crucial role in mitigating adverse SDoH by connecting patients to community resources, enhancing social and family support, and reducing food insecurity.¹⁶ However, despite the well-established role that CHWs play in addressing adverse SDoH for improved health outcomes, few interventions have utilized this strategy in a community-to-clinic linkage model to address the prevention of HTN in Black men.

Barbershops as settings for health promotion

Barbershops hold special appeal for community-based intervention programs targeting Black men, because that are a cultural institution that draws a large and loyal clientele and provides an open forum for discussion, including health, with influential peers.^{17,18} The power of barbershops for increasing HTN awareness, treatment, and control in Black men is well supported by the literature.¹⁸⁻²⁰ Furthermore, the utilization of barbershops and CHW interventions have been found to be cost-effective.^{21,22} However, there is an evidence gap in whether community-based settings, like barbershops, have the capacity (resources, time) to coordinate the complex set of changes required for adopting and sustaining a community-to-clinic linkage model.^{23,24} What

remains unanswered is the adoption, sustainability, and scalability of barbershop interventions for HTN prevention in Black men. Implementation strategies that address the organizational changes required for such redesign are sorely needed to reduce racial disparities in HTN among Black men.

Practice facilitation as a real-world implementation strategy

Practice facilitation involves both a *role* (a facilitator) and a *process* for supporting organizations to build motivation and capacity to improve organizational performance and health outcomes.^{25–28} Practice facilitators are specially trained individuals who provide external support services to help organizations overcome barriers encountered when implementing changes, and build the skills to integrate those changes into the organizational structure to improve adoption and sustainability.²⁸ Practice facilitation may mitigate barriers and support implementation of evidence-based interventions in real-world settings. Practice facilitators are specially trained individuals who provide external support services to help organizations overcome barriers encountered when implementing changes. Furthermore, these facilitators also help build the logistical skills to integrate those changes into the organizational structure to improve adoption and sustainability. The literature suggests that practice facilitation is a promising approach for scaling up effective interventions for HTN management in primary care settings.^{25,29,30} However, the impact of practice facilitation on implementing a multilevel CLIP model in barbershops to support HTN management in Black men remains untested.

Rationale for barbershop facilitation strategy to implement CLIP for the prevention of HTN among Black men

Black men have the highest prevalence of HTN largely due to adverse SDoH, including poor access to care.^{8,31} Strategies to mitigate the effect of SDoH on HTN include the use of CHWs to link people to care and navigate health systems.^{14,19,23,32} With their tremendous reach, barbershops can serve as a platform to screen Black men for HTN and navigate them to care.^{29,33} CHW interventions, barbershop-based health promotion programs, and implementation of evidence-based interventions, like CLIP, can improve HTN outcomes. These strategies require changes in processes that community-based settings may not have the resources to adopt and sustain. Practice facilitation processes applied to the day-to-day operations of barbershops (which we have coined “barbershop facilitation”) may be an effective strategy to support the implementation of CLIP in Black-owned barbershops and may mitigate process barriers to aid in HTN prevention among Black men.

This study is part of the RESTORE (Addressing Social Determinants to Prevent Hypertension) Network, an American Heart Association (AHA)-funded health equity research network focused on preventing hypertension in Black communities. The mission of the RESTORE Network is to advance the science of health equity to build a society where every person lives a healthy life free of hypertension and cardiovascular disease. The RESTORE Network investigators designed 5 randomized trials aimed at reducing racial inequities by translating efficacious interventions for HTN prevention into community settings. Each trial is testing novel strategies to implement evidence-based interventions informed by community stakeholders, addressing multiple SDoH, and using the RE-AIM implementation research framework to generate data on clinical effectiveness, cost, and sustainability of the implementation strategies that will be disseminated to

community stakeholders, health systems, and policymakers. This paper describes the rationale and protocol for one of these trials, which will test an innovative program aimed at evaluating the effect of a facilitation strategy to implement CLIP in Black-owned barbershops, for HTN prevention.

METHODS

Overview

We will conduct a cluster randomized trial in 20 Black-owned barbershops in an urban setting (Staten Island, a borough of New York City), and will enroll $N = 420$ Black men, to evaluate the effect of barbershop facilitation (BF) on the implementation of CLIP for the prevention of HTN among Black men (vs. CLIP only). The timeline for the trial is 12 months. We will conduct a pre-implementation phase of 6 months to develop a context-specific BF strategy, and we will also perform post-implementation sustainability (6 months post-trial) and cost-effectiveness analysis (projections for 10 years post-trial). The primary outcome is the change in systolic BP, with secondary outcomes change in diastolic BP, adoption of CLIP and linkage to care, and incidence of Stage 2 HTN. We hypothesize that men in barbershops randomized to the BF strategy will exhibit greater BP reduction, higher rate of linkage to care, and lower rates of incident HTN than men in the self-directed control barbershops. We also hypothesize that BF will be associated with greater adoption of CLIP. We present an overview of the barbershop workflow and participant enrollment in [Figure 1](#). We have obtained regulatory approval for the ethical conduct of this study from the NYU Langone Health Institutional Review Board. The data collected for CLIP will be made publicly available in accordance with the “open science” policies and requirements for AHA-funded research.³⁴

Conceptual frameworks

The study is guided by the Consolidated Framework of Implementation Research (CFIR) and the RE-AIM framework.^{32,33} The CFIR will guide the pre-implementation phase of the study. It is a comprehensive typology of constructs that influence the implementation of evidence-based interventions, including outer and inner settings, characteristics of individuals, and the implementation process.³² We will use CFIR to assess inner setting variables (i.e., implementation climate, leadership support), intervention characteristics, and implementation processes that underlie the adoption and sustainability of CLIP in barbershops. We will then use this information to develop the BF strategy.

The RE-AIM framework is an evaluation model to evaluate evidence-based interventions. It has 5 domains: Reach (e.g., the number of eligible organizations and people participating in the intervention), Effectiveness (e.g., impact of the intervention on desired clinical outcomes), Adoption (e.g., number of settings or individuals using the intervention), Implementation (e.g., extent to which the intervention was delivered as intended), and Maintenance (e.g., sustainability of the outcomes at the individual and organizational level over time).³³ RE-AIM has been used in a variety of settings, including for diabetes self-management,³⁵ smoking cessation,³⁶ physical activity,³⁷ and weight loss.³⁷ RE-AIM will also be used to evaluate the effect of the BF-guided CLIP program on BP reduction, as well as adoption and sustainability [Figure 1](#).

Setting

Staten Island is one of the five New York City boroughs with rich socioeconomic diversity. About 10% of the 475,000 people

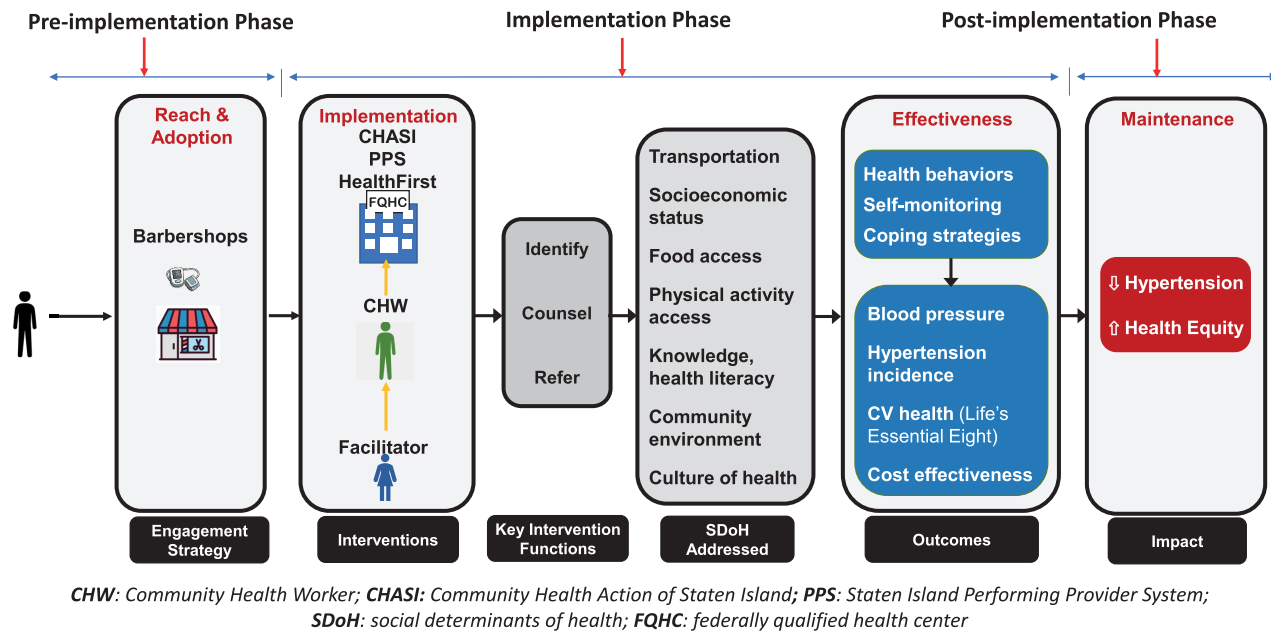


Figure 1. Study overview. Abbreviations: CHW, Community Health Worker; CHASI, Community Health Action of Staten Island; PPS, Staten Island Performing Provider System; SDoH, social determinants of health; FQHC, federally qualified health center.

in Staten Island identify as Black. Nearly 90% of all Black residents live in 1 area of the borough, which also has the highest prevalence of HTN on Staten Island.³⁸ In 2019, we partnered with NYCDOHMH and Staten Island Borough President's Office to develop an evidence-based pilot program that uses CHWs to screen Black men for HTN in Black-owned barbershops. To date, over 535 Black men have been screened for HTN in 1 barbershop, demonstrating the clear need for HTN prevention efforts in the borough.

Pre-implementation phase—developing a context-specific BF strategy

In this phase, we will qualitatively determine factors (e.g., barriers and facilitators) affecting CLIP implementation in barbershops and will develop and assess the usability of the context-specific BF strategy.

Study procedures

We will conduct semi-structured interviews with key stakeholders, community leaders, payors, and representatives from a community health network, using a CFIR-based interview guide. Questions will focus on understanding of the purpose of the CLIP program and its value; perception of the adaptability and impact of CLIP on their work; financial and logistical obstacles faced by payors; and suggestions on how they can become engaged in facilitating the adoption of the CLIP program within barbershops. Based on findings from the semi-structured interviews, we will develop a context-specific tailored BF strategy.

Implementation phase—cluster RCT

We will conduct a cluster RCT of 20 barbershops and enroll $N = 420$ Black men with elevated BP or Stage 1 HTN as defined by the 2017 AHS/ACC HTN guidelines.¹ We will compare the effect of the BF strategy with CLIP ($n = 10$ barbershops; $n = 210$ participants) vs. self-directed control (i.e., receipt of information for implementation of CLIP without the BF strategy; $n = 10$ barbershops; $n = 210$

participants) on BP reduction, HTN prevention, linkage to care, and adoption of CLIP at 12 months. Participant enrollment workflow is presented in Figure 2.

Study participants

Eligibility criteria are presented in Table 1. We will partner with 20 barbershops that would each enroll 21 men each and be randomized to the BF intervention with CLIP, or CLIP alone.

Study procedures and data collection

At baseline, research staff will confirm participant eligibility status, obtain informed consent, and complete baseline data collection including standardized BP measurements. Sociodemographic information (age, gender, ethnicity, race, primary language, employment, insurance, income, and disability) and health behaviors (alcohol use and smoking) will be collected at baseline. Following randomization, barbershops will begin the BF intervention with CLIP or CLIP alone. The list of measures and the study schedule are presented in Table 2.

BP measurement

BP for all participants were measured at baseline, 6, 12, and 18 months following baseline assessment. Study staff and CHWs were trained in proper BP measurement techniques by the RESTORE Network BP Measurement Core investigators. Training was conducted in person before any study procedures were performed. The circumference of each participant's arms were measured at the mid-point between the acromion and olecranon to determine the appropriate BP cuff size. All participants underwent office BP measured on their non-dominant arm with an Omron HEM-907XL BP device as recommended by AHA.² The Omron HEM-907XL BP device has been previously validated.^{47,48} The participant were asked to sit quietly for at least 5 minutes in a comfortable chair with the arm and back supported, with legs uncrossed, and feet flat on the floor prior to their BP measurement by the study staff in the room. At each visit, 3 BP readings

BARBERSHOP WORKFLOW

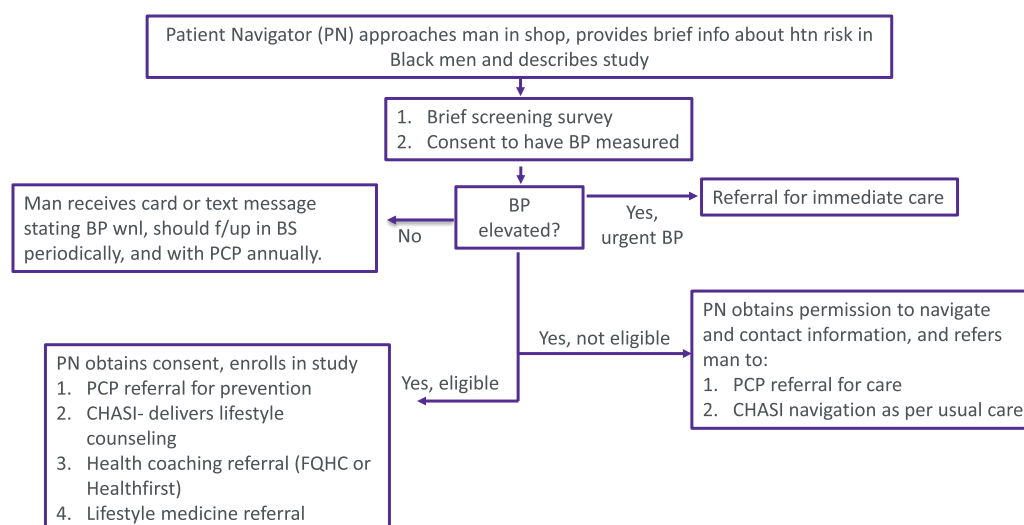


Figure 2. Enrollment workflow. Abbreviations. PN, Patient Navigator; HTN, Hypertension; BP, Blood Pressure; PCP, Primary Care Provider; CHW, Community Health Worker.

Table 1. Eligibility criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> Be at least 18 years of age on the date of data randomization A repeat customer within the last 3 months Self-identify as Black Self-identify as male Have elevated BP (120–129/<80 mm Hg, as defined by the 2017 ACC/AHA BP clinical guidelines) Have stage 1 hypertension (SBP 130–139 or DBP 80–89 mm Hg, as defined by the 2017 ACC/AHA BP clinical guidelines), but are not treated with antihypertensive medication 	<ul style="list-style-type: none"> Are under 18 years of age Have stage 2 hypertension or prescribed antihypertensive medication Have stage 1 hypertension and co-occurring diabetes, chronic kidney disease, a history of CVD (stroke or coronary heart disease), or age ≥ 65 years will not be eligible A diagnosis of end-stage renal disease A condition that interferes with outcome measurement (e.g., dialysis) A serious medical condition that either limits life expectancy or requires active management (e.g., cancer) A cognitive impairment or other condition preventing participation in the intervention An upper arm circumference > 50 cm (maximum limit of the extra-large BP cuff) Active alcohol or substance use disorder (i.e., not sober/abstinent for ≥ 30 days) Are pregnant or planning pregnancy in the next 18 months Currently nursing (breastfeeding) a child Current participation in another research study focused on reducing blood pressure Unwillingness to provide informed consent

separated by 1 minute will be obtained. The BP readings will not be visible to the study staff or participants until the procedure is complete. The 3 BP readings will be averaged to obtain mean study BP.

Table 2. Study measures at baseline, 6, 12, and 18 months

Clinical outcomes	Data source
Systolic BP (primary outcome)	Measured in barbershop
Diastolic BP	
Incident stage 2 hypertension	
Body mass index	
Patient-reported outcomes	Barbershop or telephone interview
Health-related quality of life (SF-12 Health Survey) ³⁹	
Physical activity (IPAQ) ⁴⁰	
Diet—Block screener, ⁴¹ food insecurity ⁴²	
Depressive symptoms (PHQ-9) ⁴³	
Alcohol use, smoking (self-report)	
Linkage to care—presented to clinic referred by CHW	
Social and demographic measures	Barbershop or telephone interview
Age, gender, ethnicity/race, primary language, employment, insurance, income, wealth, disability	
Health-related social needs (The Accountable Health Communities Screening Tool) ⁴⁴	
Health literacy (Electronic health literacy scale, eHEALS, ⁴⁵ and Single Item Literacy Scale, SILS) ⁴⁶	

Questionnaires

Validated questionnaires were/will be collected at baseline and at all study time points. See Table 2 for a list of study measures.

Descriptions of study arms

The CLIP program was implemented by trained CHWs by the following 3 steps: (i) Trained CHWs organized BP screenings at the barbershops. They measured the participants' body mass index (BMI) and BP using the Omron HEM-907XL BP device. Eligible men are then enrolled into the study and scheduled for lifestyle counseling, (ii) The CHWs will counsel the men on how to adopt healthy behaviors using standard motivational interviewing techniques and refer men with elevated BP to health coaching if

available, and (iii) The CHW's will link men with HTN to care via coordination with collaborating community health centers.

Barbershop-facilitated implementation strategy

The BF will be the main strategy for assisting barbershops to implement the CLIP program. We will recruit and train individuals with experience as facilitators. Facilitators are health professionals with basic nursing education and some prior clinical experience, and have a minimum of 1-year experience as a facilitator. The facilitators will work with key personnel at each barbershop to develop a plan of action for the adoption of CLIP. Finally, the BF strategy will include opportunities for shared learning across the barbershops through peer-to-peer collaborative calls. The materials and facilitation guide will be adapted from practice facilitation guides developed by our prior work. Each facilitator will work with their assigned barbershop for 12 months, and the extent of facilitation will be tracked to understand the dose of facilitation support required.

Self-directed arm

Participants in these barbershops will receive the CLIP program. However, after the initial training in the implementation of CLIP at baseline, CHWs in the self-directed arm group will not be exposed to the BF implementation strategy or receive assistance from the facilitators.

Statistical plan

Statistical analyses will be conducted at the RESTORE statistical core at the University of Alabama Birmingham, using the latest release of R. Assumptions for all statistical inferential tests and modeling will be examined including normality of residuals, equality of variance across groups, and heteroscedasticity. If assumptions are not met, transformations will be investigated (e.g., square root or natural log). If transformations are ineffective, non-parametric modeling strategies that make less strict assumptions will be applied. If any data items are more than 10% missing, we will analyze patterns of missingness and, if the data are plausibly missing at random, we will apply multiple imputations. All analyses will be intention-to-treat, regardless of intervention fidelity, or intervention intensity received. Statistical significance will be tested with an alpha level of 0.05.

Descriptive statistics for participant characteristics will be calculated overall and stratified by randomization assignment of their barbershop (self-directed or BF implementation strategy). We will estimate the intra-class correlation (ICC) of BP within each barbershop. Analyses will account for clustering of participants within barbershops with random effects. To assess if the BF intervention lowers BP compared to the self-directed control, primary analyses will fit linear mixed models containing an intercept, randomization assignment (BF strategy vs. self-directed control), time effect (6 and 12 months of follow-up), and randomization assignment by time interaction. The randomization assignment by time interaction, which measures the effect of the intervention during 12 months of follow-up, will be the primary target for inference. Since the effect of the BF intervention may not occur linearly over time, a secondary analysis will examine the time-averaged effect, which will be estimated by fitting a linear mixed model that only includes an intercept and randomization assignment (BF strategy vs. self-directed control). The primary analysis will be unadjusted with further analyses including adjustment for participant-level factors that are unbalanced at baseline. In a secondary analysis, we will test if the BF intervention reduces diastolic BP at the end of the 12-month intervention period.

Power and sample size

Power was estimated using simulations. We built a large simulated dataset with a baseline cluster level intra-class correlation (ICC) of 0.025, and a within-person correlation of adjacent BPs of 0.7 with a within-person standard deviation of 11 mm Hg, and a mean change in the intervention group of 2 mm Hg at 6 months and 4 mm at 12 months. Simulations were run allowing the number of participants per cluster to vary while maintaining the overall number of participants with evaluable data (N). For each N we ran 1000 simulations and fit linear mixed-effects models accounting for participants and sites as random intercepts. We estimated power for testing hypotheses of (i) between-group differences at 12 months, (ii) group \times time interaction for change in SBP between study groups, and (iii) between-group differences in SBP change from baseline to 12 months. With a sample size of 420 participants, 20 barbershops, and 10% of participants do not have complete data, power estimates indicated 90% statistical power to assess a difference in the change in SBP of 4 mm Hg from baseline to 12 months between those in barbershops randomized to BF vs. usual care and 91% statistical power to detect a difference in the slope over 12 months. Power estimates did not vary considerably compared to those assuming equal recruitment per cluster.

Post-implementation phase—sustainability and cost-effectiveness

We will evaluate the sustainability of the CLIP program with and without the BF implementation strategy by estimating the adoption of CLIP from the end of the intervention period (12 months) to 6 months after completion of the trial (18 months). We will model the maintenance of the adoption of CLIP in the 6 months after the completion of the implementation phase using linear regression models.

Intervention cost information will be gathered through structured interviews of study staff, financial records, and direct observation (staff and patient time spent on the intervention, salaries, and costs for travel, measurement devices, communications, etc.). We will calculate in-trial cost-effectiveness based on observed data (cost per mm Hg BP lowering or stage 2 HTN cases prevented) and project longer-term cost-effectiveness (cost per quality-adjusted life-years gained at 10 years) using the hybrid BP Control-CVD Policy Model.⁴⁹ Cost-effectiveness analysis will be conducted by the RESTORE health economics core at the University of California San Francisco and Columbia University.

DISCUSSION

The study shares the unifying central theme of the RESTORE network by testing a BF implementation strategy that addresses multilevel adverse SDoH and barriers to HTN prevention in an underserved population. RESTORE was designed to advance health equity in the United States by identifying sustainable and effective implementation strategies to deliver lifestyle interventions that prevent hypertension with a long-term impact on HTN prevention and health equity.

Our focus on barbershops is innovative because of its reach among Black men, who are underrepresented in cardiovascular research but are the most adversely affected group, compared to women and other racial and ethnic populations.¹⁻³ The use of barbershops to identify adults with elevated BP, initiate lifestyle counseling, and link them to care can mitigate barriers like mistrust of the health care system, low health literacy and poor

access to care, and ultimately prevent hypertension. Furthermore, the study engages multiple stakeholder groups in the research process, using a mixed-methods design to address their needs and priorities and increase the likelihood of program scale-up and maintenance. Evaluating the adoption and sustainability of CLIP will provide data on a potentially effective and sustainable strategy for HTN prevention among Black men using barbershops as a platform.

This project's potential impact on the field of implementation science, health equity, and HTN prevention is high. Specifically, creation of a collaborative to support external facilitation that is tailored to barbershops to support implementation of evidence-based interventions for HTN prevention will optimize sustainability. This strategy can build capacity of CHWs who can serve as change agents for patients with chronic diseases to engage with healthcare services. By engaging local stakeholders and community-based partners, including healthcare organizations and payors, we are facilitating future uptake, financing, and sustainability of the intervention. If successful, this model for implementing evidence-based interventions can be adopted and scaled up across barbershops nationally, given there are thousands of barbershops across the country, wide availability and use of CHWs, and emerging payment models that enable Medicaid reimbursement for CHW services.

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DISCLOSURE

The authors declared no conflict of interest.

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