

PROTOCOL

Design of Black Impact: A Randomized Controlled Trial Evaluating the Mechanisms Underlying Psychosocial Stress Reduction in a Cardiovascular Health Intervention

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BACKGROUND: Lower attainment of cardiovascular health (CVH), indicated by lower scores on the American Heart Association's Life's Essential 8 metrics, is a major contributor to Black men having the shortest life expectancy of any nonindigenous race/sex group. Evidence-based community interventions to improve CVH in Black men are sparse; thus, an academic–community–government–industry partnership was developed to cocreate and test a 24-week CVH intervention for Black men, Black Impact, in line with best practices for community-based participatory research.

METHODS AND RESULTS: The Black Impact intervention is delivered by health coaches, fitness trainers, and community health workers and emphasizes weekly physical activity, health education, and addressing social needs. Together, academic–community–government–industry partners will conduct a randomized, waitlist-controlled trial among 340 Black men with suboptimal CVH to determine intervention: (1) efficacy on CVH and psychosocial stress; (2) effect on individual and interpersonal outcomes; (3) effect on biological mechanisms responsive to psychosocial stress; and (4) organizational contexts and resources necessary for sustainability of the academic–community–government–industry partnership. An intervention working group of academic–community–government–industry partner representatives will guide implementation and evaluation. Upon trial completion, findings (eg, change in CVH at 24 weeks [primary], change in perceived stress at 24 weeks [coprimary], biological mechanisms, psychosocial process mediators [stress, social and interpersonal processes]) will be disseminated in scientific and lay settings.

CONCLUSIONS: Robust clinical trials are needed to test novel interventions focused on CVH equity. Black Impact will determine intervention efficacy, evaluate biological and psychosocial mediators of impact, and lay a framework for sustainability and scalability.

REGISTRATION: URL: <https://clinicaltrials.gov/>; Unique Identifier: NCT06055036.

Key Words: Black men ■ cardiometabolic health ■ health equity ■ Life's Essential 8

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Nonstandard Abbreviations and Acronyms

ACGI	academic–community– government–industry
AHA	American Heart Association
CVH	cardiovascular health
CTRA	Conserved Transcriptional Research to Adversity
LE8	Life's Essential 8

Lower attainment of cardiovascular health (CVH), indicated by the American Heart Association's (AHA) Life's Essential 8 (LE8; physical activity, diet, smoking, sleep, cholesterol, blood pressure, body mass index, and glycemia), is a major contributor to non-Hispanic Black men having the shortest life-expectancy of any nonindigenous race/sex group.¹ Gains in socioeconomic status (eg, education, income, employment status, insurance), associated with large gains in CVH in some populations, are associated with blunted gains in Black populations, especially in Black men.^{2,3} Noting that Black men continue to experience 32% higher rates of cardiovascular disease–related deaths, as compared with non-Hispanic White men,⁴ there is a dire need to focus efforts toward the design and testing of CVH-focused, community-based interventions for Black men at all socioeconomic status levels. Unfortunately, previous CVH-focused, community-engaged, and community-based participatory research interventions have lacked inclusion of the full suite of CVH metrics and a singular focus on Black men,⁵ leaving limited evidence to support the advancement of health equity in Black men.

Interventions to support CVH attainment among Black men may benefit from community-engaged approaches (eg, including community, governmental, and industry organizations as part of the research team).^{5–8} Recognizing an opportunity to “be the change,” our team of academic clinician scientists, community organizations and community members, government agencies, and industry partners (our academic–community–government–industry [ACGI] team) codeveloped Black Impact, a 24-week intervention for Black men with suboptimal CVH (described in detail below).⁹ The ACGI partners constructed the CVH-focused intervention with promotion of a healthy lifestyle in mind but also included components that would foster trusting relationships between participants and the research team.¹⁰ In 2020, the intervention was piloted among 74 Black men with suboptimal CVH. The single-arm pilot showed improvements in Life's Simple 7 score (relative to a 19% reduction in cardiovascular death), psychosocial stress (ie, perceived stress and depressive symptoms), and nonmedical health-related social needs over 24 weeks.^{9,11,12}

Given the pilot results and a stark need to create an evidence base for CVH improvement interventions in the traditionally excluded, underserved, and marginalized community of Black men, our team will conduct a 24-week randomized, waitlist-controlled trial of Black Impact. The Black Impact aims are to (1) determine intervention efficacy on CVH and psychosocial stress; (2) quantify intervention effect on individual nonclinical and interpersonal outcomes; (3) quantify intervention effect on biological mechanisms responsive to psychosocial stress; and (4) characterize the inter- and intraorganizational context and resources necessary to align, coordinate, and sustain the intervention's ACGI partnership (Figure 1). We hypothesize that this study will not only show intervention efficacy in CVH improvement but also lay an important foundation for future refinement, scalability, and sustainability outside of the Midwestern Urban area in which the intervention originated.

METHODS

Data Availability

At study completion, we will adhere to CONSORT guidelines for reporting with data from clinical trials for rigor. Data will be shared broadly.

This efficacy study (Phase III Obesity-Related Behavioral Intervention Trial) of Black Impact is funded as part of an AHA Strategically Focused Research Network on Biologic Pathways of Chronic Psychosocial Stressors on Cardiovascular Health (23SFRNPCS1067039) operating from 2023 to 2027.¹³ The study protocol is approved for the involvement of human subjects through The Ohio State University Institutional Review Board (IRB 2023H0180) and registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT06055036).

Study Design

The study design is a randomized, waitlist-controlled trial of the Black Impact intervention among Black men.

Intervention Overview

The Black Impact intervention features weekly health education, physical activity, and addressing unmet social needs over 24-weeks (Figure 2). Each participant is assigned to a team. Each team has a dedicated health coach, community health worker, participant team lead (elected by their peers), and personal trainer who will deliver the intervention components outlined below. Each week's curriculum-based session includes 45 minutes of health education led by health coaches and 45 minutes of physical activity led by personal trainers. Participants with social needs (as assessed at baseline and 12 weeks)

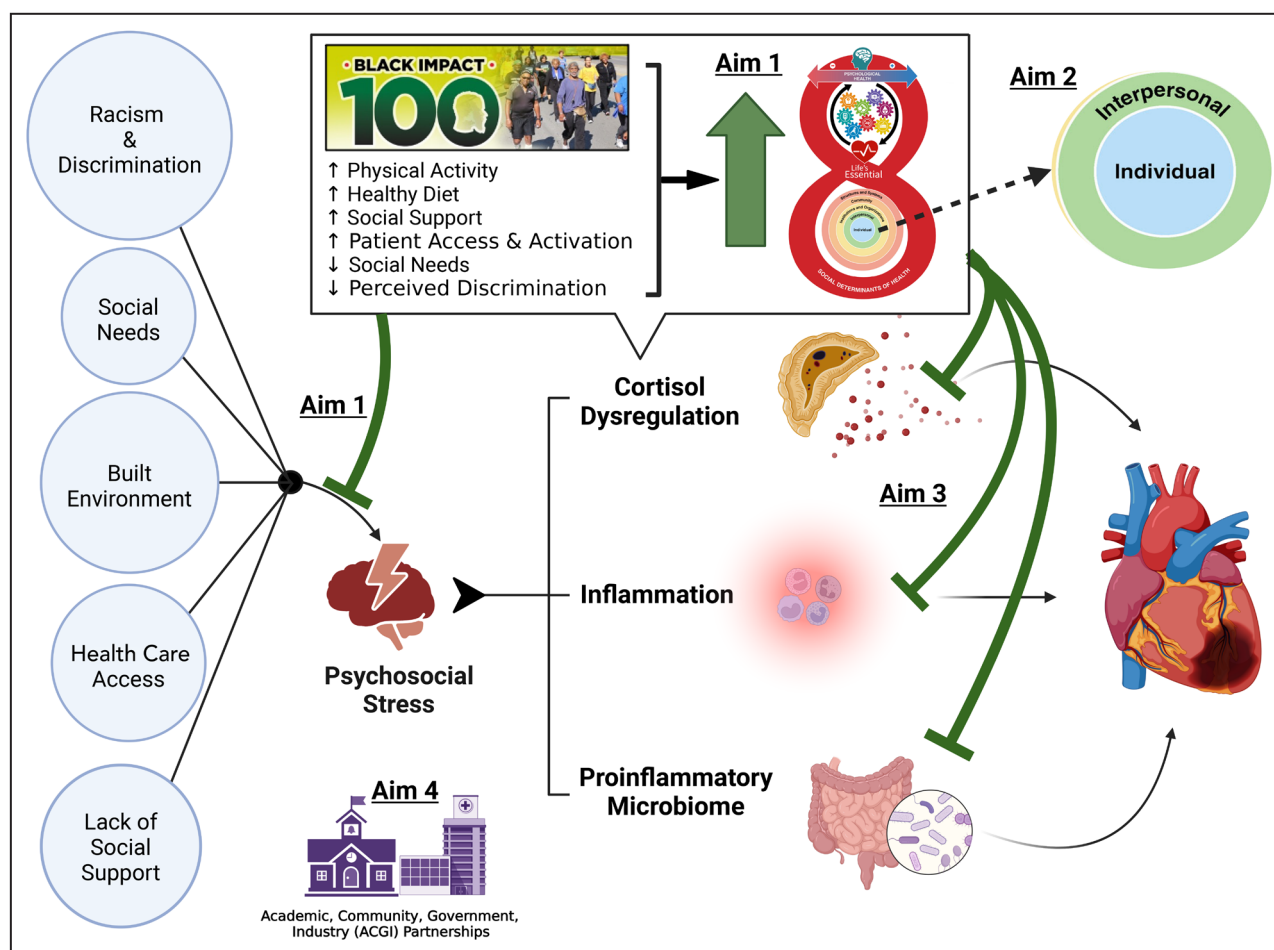


Figure 1. Black Impact aims.

The Black Impact aims are to (1) determine intervention efficacy on cardiovascular health and psychosocial stress; (2) quantify intervention effect on individual nonclinical and interpersonal outcomes; (3) quantify intervention effect on biological mechanisms responsive to psychosocial stress; and (4) characterize the inter- and intraorganizational context and resources necessary to align, coordinate, and sustain the intervention's ACGI partnership. ACGI indicates academic–community–government–industry.

are referred through a community pathways hub model to address them via engagement with an assigned community health worker. To foster continuous engagement, Black Impact also features incentives for ongoing participation in the curriculum (up to \$125).

Health Education

Black Impact is adapted from the Diabetes Prevention Program and AHA Check, Change, Control programs based on stakeholder feedback to influence target outcomes in CVH. Health coaches, all of whom are health care providers experienced in lifestyle change, implement the Black Impact curriculum across all teams.^{14,15} Health coach responsibilities include delivering education and helping participants and teams establish and monitor progress on their SMART (specific, measurable, achievable, relevant, and time-bound) wellness goals. Central to the community-based approach, the

curriculum reflects topics deemed appropriate and important by community members and stakeholders, including cooking, grocery store shopping, mental health, historical trauma, stress, financial wellness, and cancer screening (Table 1). ACGI partners colead health education sessions as indicated.

Physical Activity

Black Impact's physical activity component is based on the American College of Sports Medicine's Exercise Is Medicine curriculum including both aerobic and resistance training.⁹ Personal trainers—all of whom have preintervention training with an American College of Sports Medicine certified personal trainer on a standardized 45-minute workout that increases in intensity over the study—lead the physical activity each week. The trainers are instructed to deliver the intervention evenly across teams in terms of dose and intensity.

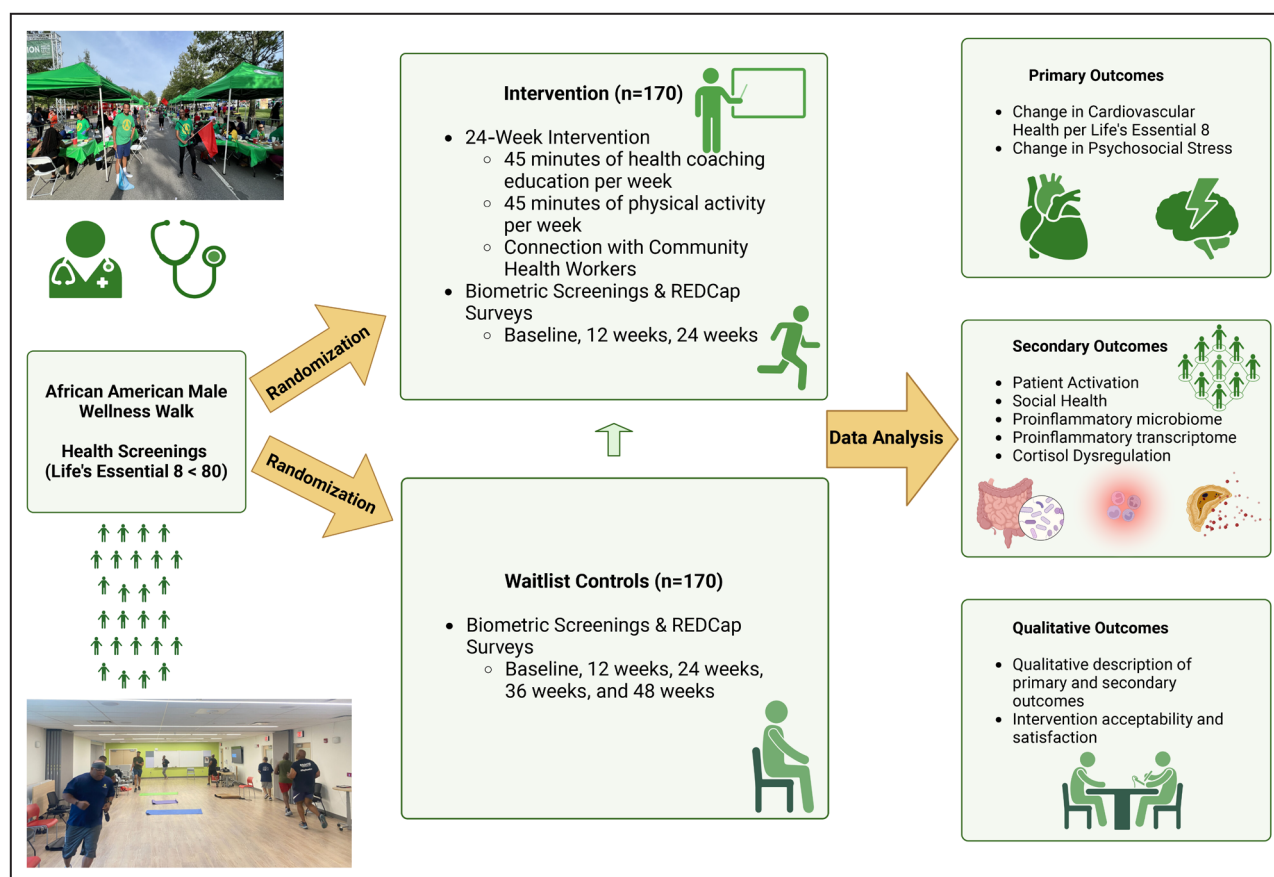


Figure 2. Black Impact study schema.

Individuals are informed about Black Impact at community events including the African American Male Wellness Walk. Individuals with Life's Essential 8 scores of <80 are recruited to the Black Impact study at informational sessions. Individuals are randomized into intervention and control groups and completed a 24-week intervention focused on health education, physical activity, addressing social needs, and engagement with primary care. Primary outcomes include change in cardiovascular health (Life's Essential 8) and psychosocial stress (perceived stress score). Additionally, secondary outcomes and qualitative outcomes are evaluated. REDCap indicates Research Electronic Data Capture.

Address Social Needs

To acknowledge the influence of social determinants of health and nonmedical, health-related social needs on CVH, the Black Impact protocol includes screening for social needs using the Accountable Health Communities Health-Related Social Needs Screening Tool.^{11,16} Individuals who screen positive for social needs or insurance challenges at baseline and 12 weeks are referred for further social needs evaluation and navigation through the Health Impact Ohio Central Ohio Pathways Hub, which uses evidence-based care coordination consistent with the Agency for Healthcare Research and Quality Pathways Community Hub model.^{17,18} The model includes 3 features: (1) a regional coordination entity that contracts with community agencies who employ community health workers to assess medical and social needs and connect individuals to community resources; (2) a comprehensive risk assessment followed by care pathway (ie, a defined action plan describing how patient needs

will be addressed) initiation and tracking by the community health worker; and (3) a linked payment from an insurance company (eg, Medicaid-managed care plans) for completion of each pathway.¹⁹ Specifically, a financial contract is attached to each standardized care pathway: With pathway completion, a community health worker confirms measurable outcomes (eg, patient accessed food) in order to receive payment.¹⁹ In Black Impact, the study participants will be referred to the Health Impact Ohio Pathways Hub using Care Coordination Systems and paired with a community health worker.¹⁹

The community health worker will conduct an initial needs assessment and guide the individual through appropriate care pathways. Community health workers are required to meet face-to-face with each client monthly as well as have a second contact (phone, text, or email) per month. Care Coordination Systems, a secure data collection platform, is used to track and flag all referrals from the Black Impact study into a program

Table 1. Black Impact Intervention Curriculum

Weeks	Community-based lifestyle program		Study measurements
	Session topics	Partners	
0	• Introduction to Life's Essential 8 and review of data on Life's Essential 8 from the annual African American Male Wellness Walk (15 min) • Purpose: Why did you join the program? What do I hope to achieve? How will healthy eating, physical activity, smoking cessation, blood pressure control, blood sugar control, and weight loss help myself and others? (20 min) • Meet the team's physical trainers (7 min)	African American Male Wellness Agency, OSU James Cancer Hospital Nurses, and Health Coaches	Complete surveys online via REDCap portal, laboratory values and baseline vitals
1	• Perform AHA MyLifeCheck (10 min) • https://www.heart.org/en/healthy-living/healthy-lifestyle/lifes-essential-8 • Organizational code: AAW100 • Overview of plan and goals of the program (15 min) • DPP Session 1: Overview • AHA Check, Change, Control, Blood Pressure Check Principles (20 min) ◦ How to take an accurate blood pressure (Check, Change, Control binder) • How to keep track? Electronic: Fitbit vs paper: journal, food diary (Check, Change, Control) (10 min)	AHA	Weight Check
2	• Life's Essential 8 Physical Activity (15 min) ◦ AHA Check, Change, Control, physical activity recommendation email • DPP Session 5: Move Those Muscles (10 min) • DPP Session 6: Being Active: A Way of Life (10 min) • Physical activity assessment, instruction, and plan development (40 min)	Health coaches and certified personal trainers	Weight check
3	• Life's Essential 8 body mass index (15 min) • Goal Weight Target Assessment (7% weight loss if BMI >25 kg/m² [See Session 1: DPP for Target Weights]) (15 min) • AHA Check, Change, Control physical activity email • Physical Activity Instruction (45 min)	Health coaches	Weight check
4	• Life's Essential 8 Dietary Intake (DASH, American Heart Association, and DPP dietary recommendations) (15 min) ◦ Sneaky Salt Video and Sodium Pledge (Check, Change, Control)	Eat to Treat	Weight check
	• https://www.youtube.com/watch?v=YR81aziXRfw • DPP Session 2: Be a Fat, Calorie, and Salt Detective (15 min) • Physical activity (45 min)		
5	• Life's Essential 8 blood pressure (10 min) • AHA Check, Change, Control; blood pressure check (20 min) ◦ What can I do to improve my blood pressure (Check, Change, Control binder) ◦ https://www.heart.org/en/health-topics/high-blood-pressure/changes-you-can-make-to-manage-high-blood-pressure/what-you-should-know-about-high-blood-pressure-and-medications (Check, Change, Control) • Physical activity (45 min)	AHA	Weight, blood pressure check
6	• Life's Essential 8 cholesterol (10 min) • DPP Session 3: 3 Ways to Eat Less Fat and Fewer Calories (10 min) • DPP Session 4: Healthy Eating (10 min) ◦ Season of Eating infographic (Check, Change, Control) ◦ https://recipes.heart.org/ ◦ (Check, Change, Control; try 1 new recipe/wk) • Physical activity (45 min)	Health coaches	Weight check

(Continued)

Table 1. Continued

Weeks	Community-based lifestyle program		Study measurements
	Session topics	Partners	
7	- Life's Essential 8 blood sugar (20 min) - What is prediabetes? - Review of how Sessions 1–6 impact blood sugar (10 min) - Physical activity (45 min)	Health coaches	Weight check
8	- Life's Essential 8 sleep (15 min) - Importance of 7–8 h of sleep (30 min) - Physical activity (45 min)	AHA	Weight check
9	- Historical Trauma, Stress Management and Mental Health Strategies and Resources (28 min) - DPP Session 15: Stress Management (5 min) - Intro to Real Men Real Talk from the African American Male Wellness Agency (2 min) - Physical activity (45 min)	Columbus Public Health Care Coalition African American Male Wellness Agency	Weight check
10	- DPP Session 7: Tip the Calorie Balance (15 min) - DPP Session 8: Take Charge of What's Around You (15 min) - Physical activity (45 min)	Health coaches	Weight check
11	- Life's Essential 8 smoking (15 min) - Smoking Prevention and Cessation, Direct Impact of Smoking, Second Hand, Third Hand, Resources for Smoking Cessation, Quit Line (30 min) - Physical activity (45 min)	Columbus and Franklin County Public Health	Weight check
12	Midway Celebration with healthy snacks, midway awards	African American Male Wellness Agency, OSU James Cancer Hospital Nurses, and Health Coaches	Complete surveys online via REDCap and Biometrics
13	- Cooking demonstration: The James Mobile Education Kitchen (45 min) - Physical activity (45 min)	OSU Nutrition Services	Weight, blood pressure check
14	- DPP Session 9: Problem Solving (15 min) - DPP Session 10: 4 Keys to Healthy Eating Out (15 min) - DPP Session 11: Talk Back to Negative Thoughts (15 min) - AHA Check, Change, Control; blood pressure check - Stress and blood pressure (email link) - Physical activity (45 min)	Health coaches	Weight, blood pressure check
15	- DPP Session 12: The Slippery Slope of Lifestyle Change (30 min) - Physical activity (45 min)	Health coaches	Weight check
16	- Introduction to Clinical Trials (10 min) - Community Scientist Academy Program (10 min) - Introduction to ResearchMatch (15 minutes) - Physical activity (45 min)	OSU Center for Clinical and Translational Science	Weight check
17	- DPP Session 13: Jump Start Your Physical Activity (30 min) - Physical activity (45 min)	Health coaches	Weight check
18	- AHA Check, Change, Control; blood pressure check (30 min) 5 Steps to Loving Exercise ... or At Least Not Hating It (Email) - Physical activity (45 min)	Health coaches	Weight, blood pressure check
19	- DPP Session 14: Making Social Cues Work for You (30 min) - Physical Activity (45 min)	Health coaches	Weight check
20	- Money Matters: Financial Wellness Strategies (45 min) - Dining Out Doesn't Mean Ditch Your Diet (Check, Change, Control) - Physical activity (45 min)	Bank of America	Weight check
21	Grocery store tour	OSU Nutrition Services	Weight check

(Continued)

Table 1. Continued

Weeks	Community-based lifestyle program		Study measurements
	Session topics	Partners	
22	- Importance of Cancer Screening: The American Cancer Society (30 min) - AHA Check, Change, Control; blood pressure check (15 min) - Physical activity (45 min)	American Cancer Society	Weight, blood pressure check
23	- DPP Session 16: Ways to Stay Motivated (30 min) - AHA Check, Change, Control: Staying Motivated for Fitness - Physical activity (45 min)	Health coaches	Weight check
24	- Black Impact graduation - Surveys and biometrics - Celebration/Black Impact certificates	African American Male Wellness Agency, OSU James Cancer Hospital Nurses, and Health Coaches	Complete surveys online via REDCap and Biometrics

AHA indicates American Heart Association; BMI, body mass index; DASH, Dietary Approaches to Stop Hypertension; DPP, Diabetes Prevention Program; OSU, The Ohio State University; and REDCap, Research Electronic Data Capture.

designation to aggregate all pertinent data. The Health Impact Ohio Pathways Hub will then generate a report articulating social needs assessments, and open and completed care pathways for each applicable study participant.

Incentives

Throughout the intervention, participants have access to resources that promote engagement with the curriculum including healthy food samples (prepared for tasting during scheduled sessions), fitness smartwatches, workout bands, and an Omron blood pressure cuff (Omron Corporation, Kyoto, Japan) to self-monitor blood pressure (used as a tool to share readings with health coaches and primary care providers to adjust medical therapies as needed). All participants receive a \$25 gift card incentive for participation in biometric and data collection activities at baseline and 12 and 24 weeks (total \$75).

Intervention Conceptual Framework

The Black Impact curriculum is grounded in social cognitive theory, with the broader intervention components justified by a multilevel framework consistent with the socioecological model. Social cognitive theory posits, in part, that successful performance of a behavior depends on an individual's behavioral capability (as well as cognitive and environmental influences) via 4 domains: (1) observational learning, (2) reinforcement, (3) self-control, and (4) self-efficacy.^{20,21} Black Impact provides health education through the Diabetes Prevention Program - and an AHA Check, Change, Control-aligned curriculum that clearly explains how certain behaviors, clinical care engagement, and addressing social needs will help participants improve CVH (ie, fostering accurate outcome expectations via improved knowledge

and beliefs). The intervention's health education curriculum will develop participants' skills to engage in behavioral lifestyle modification and guideline-based clinical care (ie, via observational learning). Team-based coaching sessions and physical activity will support development of new skills that will ideally yield meaningful improvements in personal confidence and competence to enhance their health-related behaviors (ie, improve health-related self-efficacy). Application of social cognitive theory at the individual level enhances health-related knowledge, beliefs, and self-efficacy; the group-based nature of Black Impact advances social well-being and cultivates interpersonal reinforcement for behavioral maintenance; involvement of local ACGI partners in curricular implementation encourages collaborative capacity among organizations (ie, in the community environment) toward long-term coordination of health equity efforts; and delivery of the intervention in community settings enhances long-term sustainability. Importantly, Black Impact allows ACGI partners to apply their specific expertise, helping to create a sustainable approach for supporting comprehensive lifestyle education and support among Black men facing CVH inequities (Table 1).

STUDY SETTING

Each Black Impact team meets weekly at a central meeting location (Columbus Recreation and Park centers) near where participants live or work. Location access is made available through the ACGI partnership.

Study Population

Study inclusion criteria include (1) Black men (self-report); (2) adult aged ≥ 18 years; (3) LE8 score < 80 at screening (Table 2); (4) English speaking; (5) lives in Metropolitan Columbus, Ohio; and (6) no health

Table 2. Measurement and Scoring of American Heart Association's Life's Essential 8

CVH metric	Method of measurement	Scoring	
Diet	MEPA questionnaire (range, 0–16)	Points 100 80 50 25 0	Quantile of MEPA score ≥ 95th percentile 75th–94th 50th–74th 25th–49th 1st–24th
Physical activity	1. In the past 30 days, other than the activities you did for work, on average, how many days per week did you engage in moderate exercise (like walking fast, running, jogging, dancing, swimming, biking, or other similar activities)? 2. On average, how many minutes did you usually spend exercising at this level on 1 of those days?	Points 100 90 80 60 40 20 0	Minutes ≥ 150 120–149 90–119 60–89 30–59 1–29 0
Smoking	1. Smoking status (tobacco; check all that apply)? A I currently smoke B I vape C I quit smoking in the past year D I quit smoking 1–4 y ago E I quit 5+ y ago F I have never smoked 2. Do you live with an indoor smoker? A Yes B No	Points 100 75 50 25 0 subtract 20 (if score ≥ 25) for living with active indoor smoker	Status Never Smoker Quit ≥ 5 y Quit 1 to <5 y Quit <1 y, or current inhaled nicotine-delivery system use Current smoker
Sleep	How many hours do you sleep per night on average?	Points 100 90 70 40 20 0	Hours of Sleep 7 to <9 9 to <10 6 to <7 5 to <6 or ≥ 10 4 to <5 <4
Body mass index	Weight in kg/height in m ²	Points Non-Asian Americans 100 70 30 15 0 Asian Americans 100 70 50 25 0	kg/m ² < 25 25.0–29.9 30.0–34.9 35.0–39.9 ≥ 40.0 < 23.0 23.0–24.9 25.0–29.9 30.0–34.9 ≥ 35.0
Non-HDL-C	Enzymatically measured total cholesterol minus HDL-C	Points 100 60 40 20 0 If drug-treated level, subtract 20 (if score ≥ 20)	Non-HDL-C (mg/dL) < 130 130–159 160–189 190–219 ≥ 220
Blood glucose	Glycated hemoglobin	Points 100 60 40 30 20 10 0	% < 5.7, no diabetes 5.7–6.4, no diabetes < 7.0, with diabetes 7.0–7.9, with diabetes 8.0–8.9, with diabetes 9.0–9.9, with diabetes ≥ 10.0, with diabetes

(Continued)

Table 2. Continued

CVH metric	Method of measurement	Scoring
Blood pressure	Appropriately measured systolic and diastolic blood pressure (mm Hg)	Points mm/Hg 100 < 120/<80 75 120–129/<80 50 130–139 or 80–89 25 140–159 or 90–99 0 ≥160 or ≥100 If drug-treated level, subtract 20 (if score ≥20)
Overall Life's Essential 8 Score		Average of the scores for the Life's Essential 8 individual metrics

HDL-C indicates high-density lipoprotein cholesterol; and MEPA, Mediterranean Eating Pattern for Americans.

care provider–imposed limitations on physical activity. The study population for evaluation of the ACGI partnership's alignment and potential for sustainability includes ≥1 representatives from all existing ACGI partners, including both individuals involved in implementation and those with organizational leadership roles and authority over resource and effort allocation.

Recruitment

Our recruitment approach is informed by our experience recruiting individuals of African ancestry to a number of observational and clinical trial studies.^{8,9,19,22,23} Our approach focuses on potential participants engaged in community health activities; as with recruitment efforts for the Black Impact pilot study, we will partner with the African American Male Wellness Agency of Columbus, Ohio, to identify potential participants at annual walks where Black men are invited to engage in LE8 assessment. Of the 700 to 1300 Black men screened annually, we anticipate that two thirds of those screened will meet the study's eligibility criteria. Potential participants for Black Impact will be invited to attend informational events at community locations to further discuss the study, review the consent documents, and, for those interested, provide written informed consent. Those enrolled are randomized to either the intervention arm or a waitlist control arm and assigned to a team on the basis of geographic location. The process will be repeated annually to achieve enrollment of 340 participants (Figure 3). The study schema is represented in Figure 2.

Retention

We expect no more than a 10% dropout (attrition) rate on the basis of findings of the Black Impact pilot study.⁹ Strategies applied will include promotion of social support through fostering trusting relationships with the study team and team members, dedicated engagement with participants on a weekly basis during Black

Impact sessions and via text message reminders about upcoming sessions, timely feedback after data collection, and incentivization described above. Every effort will be made to ensure that participants complete the 24-week intervention.²⁴ For example, should a participant's availability change, we will arrange for the participant to integrate into another team that meets at a time that is more conducive to the participant's availability.

Data Collection and Measurement

Participant assessment will occur at baseline and 12 and 24 weeks in the intervention and waitlist control groups and 36 and 48 weeks in the waitlist control group only. Biometric information collected will include glycated hemoglobin (Afinion hemoglobin A_{1c} cartridge and Afinion 2 Analyzer; Abbott Laboratories, Chicago, IL); lipids, including total cholesterol and high-density lipoprotein (Cholestech LDX TC-HDL Cassettes and Analyzer; Abbott Laboratories, Chicago, IL); and blood pressure (Omron 5 Series Upper Arm Blood Pressure Monitor). Validated surveys will be used to capture all LE8 indices and complementary individual- and interpersonal-level factors via Research Electronic Data Capture. Survey data include Health-Related Quality of Life,²⁵ self-rated health, the Mediterranean Eating Pattern for Americans,²⁶ Pittsburgh Sleep Quality Index,²⁷ International Physical Activity Questionnaire,²⁸ Centers for Medicare and Medicaid Services Accountable Health Communities Health-Related Social Needs Screening Tool,¹⁶ Perceived Stress Scale,^{29,30} Center for Epidemiologic Studies Depression Scale,³¹ Insignia Health Patient Activation Measure,³² Patient-Reported Outcomes Measurement Information System Social Function scales,³³ Patient-Reported Outcomes Measurement Information System Social Relationships scales,³³ General Ethnic Discrimination scale,³⁴ and Philadelphia Adverse Childhood Events survey.³⁵ Quantitative, self-reported measures are collected at each time point using an

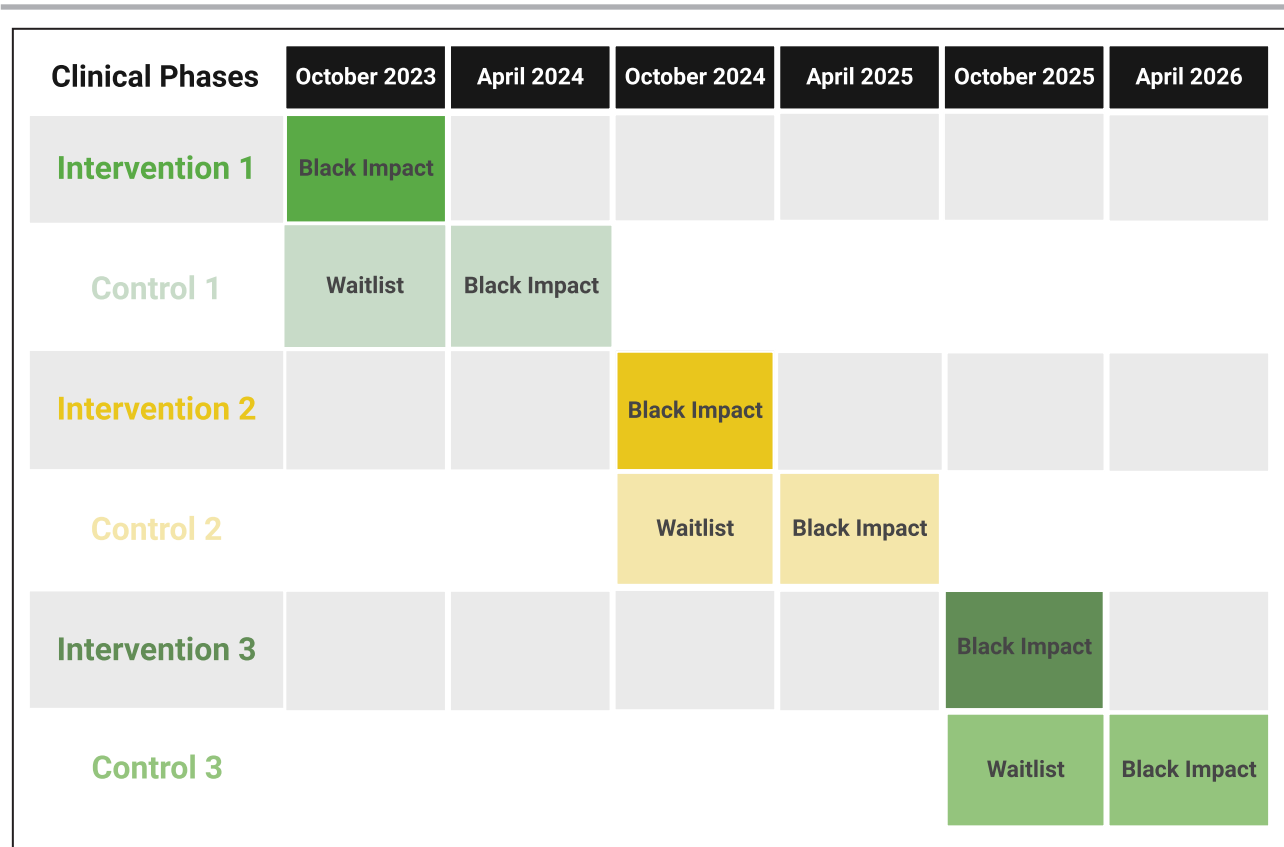


Figure 3. Black Impact intervention and waitlist control group study timeline. Black Impact includes an intervention group that receives the Black Impact intervention from October to April and a waitlist control group that receives usual care from October to April. From April to October the waitlist control group receives the Black Impact intervention in line with ethical principles for community-based participatory research. Three sets of Black Impact cohorts will be recruited over the course of the 4-year study.

electronic survey interface (Research Electronic Data Capture).

The sociodemographic data collected will include age, education, race, ethnicity, employment status, insurance status, and annual income. The self-reported health history data collected include hypertension, type 2 diabetes, hyperlipidemia, smoking status, physical activity minutes per week, diet rating (Poor, Fair, OK, Good, or Excellent), average hours of sleep per night, and current medications. Biospecimens will be collected for analysis of psychosocial stress-related biomarkers. Cortisol regulation will be assessed using hair cortisol concentrations.³⁶ Briefly, a section of hair will be selected at the posterior vertex of the cranium. The section will be combed, gently pulling 30 to 50 strands taut. The strands will be cut as close to the scalp as possible with salon-grade scissors. The sample will be placed in aluminum foil at room temperature, with prior studies indicating long-term sample stability under this condition. Proximal 3-cm hair segments (reflecting about 3 months) will be isolated, washed, dried, and milled. Cortisol will be extracted from 50 mg of powdered hair, followed by alcohol evaporation and sample reconstitution. Supernatant cortisol concentrations will then be quantified, in duplicate, by ELISA.

Leukocyte gene transcripts pertinent to glucocorticoid signaling and regulation will also be quantified. Briefly, whole blood will be collected into PAXgene blood RNA tubes (Qiagen, Germantown, MD), maintained at room temperature for 36 hours, transferred to -20 °C and then -80 °C for storage. RNA will be isolated using PAXgene Blood RNA kits per manufacturer instructions, which includes nucleic acid pelleting, washing, resuspension, and purification. RNA quantity and purity will be examined using the TapeStation Bioanalyzer. Total RNA sequencing with globin depletion will be performed. Specific to glucocorticoid signaling, we will evaluate the expression of target genes in the glucocorticoid pathway including *NR3C1*, *NR3C2*, *STAT1*, *STAT3*, *FKBP5*, and *HSD11B1*. Inflammatory activity will also be assessed at baseline and 12 and 24 weeks, focusing on leukocyte gene transcripts pertinent to the innate immune response. Combined with the glucocorticoid panel, the expression of 19 target inflammatory genes (*CXCL8*, *FOS*, *FOSB*, *FOSL1*, *FOSL2*, *IL1A*, *IL1B*, *IL6*, *JUN*, *JUNB*, *JUND*, *NFKB1*, *NFKB2*, *PTGS1*, *PTGS2*, *REL*, *RELA*, *RELB*, *TNF*) will be quantified. Following background subtraction and normalization of the raw data, inflammatory and antiviral gene activity will be

operationalized as an inflammatory composite score, an antiviral composite score, and global score reflective of an index termed the Conserved Transcriptional Research to Adversity (CTRA; inflammatory composite score minus antiviral composite score).³⁷ The sets of transcripts are theoretically derived, capturing activity of key pathways pertinent to cardiovascular disease and supported by literature on the CTRA and related frameworks in human social genomics. Data in support of the notion of a stress-responsive CTRA have been building, including in experimental studies showing a positive response to stress reduction.^{37,38}

The gut microbiome will be collected and examined. For stool collection, participants will be provided with a collection hat, sterile collection tube, and applicator stick. The collection hat is placed directly on the toilet and participants will excrete into the hat, at which point the applicator stick will be used to transfer a golf ball-sized portion of stool into the collection tube. Samples will be kept refrigerated for a maximum of 24 hours, in the presence of an ice pack, until transfer to a locked -80°C freezer, where they will be kept until DNA is isolated and sequencing is performed. Stool DNA will be isolated using the Qiagen PowerFecal Pro DNA Kit per manufacturer's instructions (Qiagen Corporation). Sequencing will be performed using a short-read Illumina platform, resulting in $2\times 300\text{bp}$ paired-end reads (Illumina, San Diego, CA). Resulting sequences will be delivered to study staff in .fastq format, which will be demultiplexed in QIIME2 and denoised using dada2c.^{39,40} Primary alpha metrics, including Pielou's Evenness, Shannon's Diversity Index, and Faith's Phylogenetic Diversity, will be performed using QIIME2. Likewise, β diversity, using weighted and unweighted Unifrac distance metrics as well as the Bray–Curtis distance metric, will also be performed in QIIME2. Taxonomy will be assigned with the most recent Silva database and taxonomic differential abundance analysis will be performed using a combination of ANCOM on QIIME2, LEfSe, and Songbird.^{39,41–43} Finally, longitudinal analysis will be performed using the q2-longitudinal tool set available on QIIME2.

Upon study completion, participants will be invited to join qualitative exit surveys (focus groups) to understand participants' experiences with and views of the Black Impact intervention. We will use a semistructured interview protocol designed to understand factors contributing to reach (ie, factors contributing to their enrollment and retention in and acceptability of Black Impact), dose (ie, degree of engagement in intervention activities), and related context (ie, individual and social factors influencing both engagement and potential for behavioral maintenance). We will conduct up to 8 to 12 focus groups, each with 8 to 10 participants. Focus groups will last ≈ 60 to 90 minutes, and each participant will receive a \$25 gift card for participation. All

focus groups will be audio-recorded and transcribed for rigorous analysis.

Finally, an organizational assessment of the partnerships that underly Black Impact will be performed. The organizational assessments will use one-on-one semistructured interviews with (1) organizational leaders with decision-making authority about engagement and resource allocation (eg, chief operating officers, directors), and (2) organizational staff involved directly in implementing the Black Impact curriculum. Interview participants will be purposively sampled on the basis of organization and role and interviewed in the weeks following engagement in the Black Impact curriculum to afford direct reflection of their and their organization's contribution. This component of the study aims to understand the experience of engaging in ACGI partnerships, like Black Impact, that endeavor to coordinate social needs support and provide services like education and health care for Black men and other underserved populations. Interview questions will focus on understanding contextual factors and processes at the organizational, community, and policy levels that may enable or challenge organizational engagement in and support of the Black Impact intervention and similar programs. Specific topics will include partnership motivation, goal and incentive alignment, facilitators of partnership success, conflict management and resolution, and sustainment and scale planning. All will be audio-recorded and transcribed verbatim for rigorous analysis. Interviews will be conducted in person when possible or virtually and last ≈ 1 hour. We will conduct 20 interviews in year 1 of the trial, and 20 additional interviews in year 3 of the trial. Year 3 interviews will focus on sustainability and continued willingness to engage in ACGI partnerships.

Primary Outcome Analyses

The primary objective of our study is to evaluate the efficacy of the 24-week Black Impact program in improving CVH. Given this focus, the primary outcome for the randomized controlled trial is change in CVH, per LE8 score, at 24-week follow-up, and the coprimary outcome is change in psychosocial stress as measured by the Perceived Stress Scale. Following the analytic approach in our pilot study,⁹ change in LE8 measures and perceived stress will be calculated using a linear mixed-effects model to evaluate changes from baseline. Study wave will be a covariate in the models. The primary analysis will contain data from baseline (0 weeks), during intervention (12 weeks), and after intervention (24 weeks). The models will assess differences between waitlist control and intervention participants using an interaction between time and treatment indicator. A secondary analysis will examine within-group changes over time for both treatment and control arms. Residual plots will examine model

assumptions and model fit, with sensitivity analysis using bootstrapping approaches. The mixed model naturally handles data that are missing at random when including covariates associated with the probability of missing values. Patterns of missing data will be further explored to determine whether nonrandom dropout exists (eg, due to patient decline in health). While not expected, in the event nonrandom dropout is evident, joint models or pattern mixture models will account for the dependent nature between the longitudinal and event process.

Power and Sample Size Calculations

Power and sample size for the trial was determined on the basis of the change in CVH scores from LE8 (0–100 score [Table 2]) using a 2-sample *t* test based on the effect sizes and SDs informed by the Black Impact pilot study and a review of the literature for control changes in Life's Simple 7 (Faith! trial).^{44,45} We assumed a 10% dropout rate based on the Black Impact pilot study.⁹ Thus, with a total study size of 340 (170 per arm), this study is powered to detect a main effect size of 0.32 (0.42 [Black Impact pilot] to 0.1 [Faith! intervention controls]=0.32), at an 80% power with an α of 0.05 with 10% dropout. This study size also provides 80% power ($\alpha=0.05$) to detect a true difference in Perceived Stress Scale (assume control group: mean, 14.45 $\pm$ 7.3) of 2.3 between groups using a 2-sided, 2-sample *t* test.

SECONDARY OUTCOME ANALYSES

The change in secondary outcomes including individual LE8 metrics, depressive symptoms, health-related quality of life, social function, discrimination, and so on at 12 and 24 weeks will be examined using linear mixed models with subject-level random effects, which account for longitudinal measures on each subject, with treatment by time interactions testing differences in changes over time across study arms. A model-fitting strategy will follow similar procedures, checking model specification and fit by examining concordance with distributional assumptions.

Biological Mediators

Linear mixed-effects models will evaluate changes in (1) hair cortisol, (2) inflammation (stress-induced activation of the CTRA RNA profile), and (3) gut microbiome at 12 and 24 weeks. For the CTRA profiling, repeated-measures contrast scores will be used if there are challenges related to nonnormality and weakly expressed genes.

Organizational Partnership Assessment

Interview data will be analyzed using an iterative process throughout the data collection phase, involving

reading transcripts, reviewing the literature, and discussing findings among investigators as data collection progresses. A coding team involving at least 2 coders will create a preliminary codebook defining broad categories of findings based on the interview guide and from reviewing the transcripts. Following a second round of coding, data from these broad codes will be classified into themes following Conastas' constant comparison method.^{46,47} The coding team will meet throughout the coding process to ensure consistency of coding and review any emergent themes, consistent with a grounded theory approach.⁴⁸ Nvivo software will be used to facilitate coding.

ETHICAL CONSIDERATIONS

All participants will undergo informed consent obtained by the study principal investigator or coordinator. The study-related information will not be used, and the participant will be withdrawn on declination of participation. No deception will be used, and we will answer all questions in detail. Participants may leave the study for any reason without effect to their care. Thus, informed consent is a continual process. The consent form will adhere to the single institutional review board of record at The Ohio State University, state and federal requirements, and the Health Insurance Portability and Accountability Act Privacy Rule. A copy of the signed consent form will be provided to the patient and placed in the patient's medical record.

Venipuncture will be performed by trained individuals; therefore, the risk of experiencing side effects regarding the amount of blood drawn is minimized.

There is an elevated risk of cardiopulmonary events and muscle or bone injury during physical activity bouts. Inclusion criteria specify that all participants must not have any provider-imposed limitations on physical activity to mitigate these risks.

Precautions will be taken throughout the project to minimize any risk to confidentiality for participants. Participants will receive a unique study identifier. Digital recordings of interviews, transcripts, and raw survey data will be stored on a password-protected computer on a secure network.

If treatment is needed regarding participation in the research study, the participant will contact the multiple principal investigators/study team for needed care.

DISCUSSION

The Black Impact study will test an evidence-based intervention among Black men, the most CVH–mortality disparate population in the United States. The Black Impact intervention will use a novel approach using

an ACGI partnership and incorporating community-based, multilevel, multisystem resources for Black men to learn healthy lifestyle education, engage in physical activity, and address social needs. This study will be purposely conducted to bring forth evidence to scaffold future implementation studies and inform effective approaches to reduce CVH disparities among Black men. Key aspects of how the study will bring forth evidence are in its design, exploration of how Black Impact works mechanistically, and attention to scalability and sustainability.

The design of the study will provide evidence on the interplay between CVH and interpersonal influences. It is widely accepted that social determinants of health affect health outcomes.¹¹ CVH is negatively associated with stress.⁴⁹ A recent study comparing Black Americans and White Americans found that differences in CVH were explained partially by income, marital status, and chronic stress burden.⁵⁰ It is also increasingly proposed that social relationships, specifically lack thereof, may be linked to greater cardiovascular death.⁵¹

Further exploration of changes in the AHA's LE8 and underlying mechanistic pathways is critical to advance the mechanistic understanding of Black Impact, which may allow for further tailoring and personalization of the intervention. Comprehensive assessments of multiple omics in intervention studies including the gut microbiome and RNA transcriptomics are limited in Black men. The Black Impact study offers a culturally sensitive approach to engage Black men in a comprehensive clinical research study.⁵²

Black Impact is uniquely supported by institutions and organizations with national networks and affiliates (eg, municipal recreation and parks departments, regional AHA offices, national banks). The present study will elucidate best practices for multisectoral collaborations to support Black men's attainment of CVH. The organizational assessment will also provide guidance for the development and implementation of similar partnerships across these networks as other communities seek to create ACGI partnerships to redress existing health inequities. To date, sustaining ACGI partnerships and programs has been stymied by a lack of evidence around partnership sustainment; addressing this critical gap is at the core of this study's organizational assessment aim.

In sum, the Black Impact study will provide evidence to inform hybrid effectiveness and implementation science studies that bring health behavior change from clinics to communities.⁵³

LIMITATIONS

The implementation of Black Impact takes place within a single geographic area with defined ACGI partnerships. However, this environment provides a useful

real-world setting to test the efficacy of the interventions before multisite effectiveness and implementation trials. The challenge of enrolling Black men who are underrepresented in research is acknowledged. The experience of the research team in recruiting, enrolling, and retaining Black men in research with the support of ACGI partners is expected to facilitate achievement of sufficient enrollment.⁵² There is potential for contamination across study arms; that is, participants enrolled in Black Impact may learn about Black Impact-related topics through other avenues and may be referred to other community organizations that address social needs, including the possibility that participants not randomized into the active intervention may receive a referral to the Pathways Community Hub before the end of their waitlist control period. However, we believe that these effects will have minimal impact on the primary and secondary study outcomes.

CONCLUSIONS

We expect Black Impact, a novel, community-based intervention targeting CVH attainment among Black men, to provide a scalable model for improving CVH and psychosocial stress at the individual and population level. Additionally, analysis of the interpersonal and biological processes and pathways by which the intervention advances CVH are critical to advance the mechanistic understanding of the intervention. The proposed study aligns with the AHA's commitment to addressing CVH equity through innovative, multimodal solutions.⁵⁴

ARTICLE INFORMATION

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Disclosures

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