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Compendium

Design of the Equity in Prevention and Progression of Hypertension by Addressing Barriers to Nutrition and Physical Activity Study: A Cluster Randomized Trial

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Background: High rates of hypertension and poverty in the rural south contribute to health disparities with Black adults experiencing higher rates of cardiovascular disease than White adults, underscoring the need to identify prevention strategies.

Methods: The equity in prevention and progression of hypertension by addressing barriers to nutrition and physical activity (EPIPHANY) study is a cluster randomized controlled trial testing a multilevel intervention to reduce barriers to a healthy lifestyle to lower blood pressure (BP) among rural, Black adults. Health education fairs offered to 20 churches in the Alabama Black Belt are being used to screen and enroll adults with elevated BP or stage 1 hypertension (systolic BP 120–139 mmHg and diastolic BP < 90 mmHg) who are not recommended for antihypertensive medication, according to the 2017 American College of Cardiology/American Heart Association BP guideline. Participants (n = 240) in churches randomized to the control condition are offered access to online resources including cooking and exercise classes. Participants (n = 240) in churches randomized to the intervention are receiving access to online resources; telephone-based peer support for lifestyle modification; funding for churches to develop programs to address food access and/or barriers to physical activity; and training of church members to serve as church champions to deliver training for church members on lifestyle modification. We will employ a Type 1 hybrid implementation-effectiveness design to assess effectiveness and implementation.

Conclusions: The EPIPHANY study is designed to prevent hypertension among rural, Black adults by addressing structural and individual barriers to lifestyle modification through peer support.

Keywords: blood pressure; hypertension; lifestyle modification; prevention; social determinants of health

Graphical Abstract



*Based on NIMHD Research Framework

CC: Community Coordinator; BP: blood pressure; RE-AIM, RE-AIM: Reach, Effectiveness, Adoption, Implementation, Maintenance Framework

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About 55% of Black adults in the United States have hypertension, the nation's leading cause of the cardiovascular disease (CVD).^{1,2} Clinical trials have shown that lifestyle interventions like dietary approaches to stop hypertension diet and increasing physical activity reduces the risk for hypertension.^{3,4} However, their adoption is suboptimal among Black adults.⁵ Negative social determinants of health (SDOH) including a lack of education on health behaviors, low socioeconomic status, lack of transportation, and limited access to heart-healthy foods and physical activity spaces contribute to this research-to-translation gap.⁶

The Black Belt is a southern, predominantly rural region known for its high level of poverty and largely Black population.7 This region has one of the highest prevalences of hypertension in the United States,8 emphasizing the need for prevention efforts. The prevalence of food insecurity, defined as "limited or uncertain availability of nutritionally adequate and safe foods" in Alabama's Black Belt is 3 times the national average.9 Black Belt residents also encounter negative SDOH as barriers to adopting dietary approaches to stop hypertension dietary patterns and participating in guideline-recommended physical activity, including unstable transportation, poor social support, and limited recreational facilities.^{10,11} Therefore, approaches to lower blood pressure (BP) that acknowledge and address the SDOH barriers, and meet individuals where they work, live, and worship, are particularly well suited for the Black Belt.¹² Implementation strategies that address individual, social, and environmental determinants of lifestyle behaviors among Black adults in the Black Belt could increase equity in BP and prevent the development and progression of hypertension.

To address the need for hypertension prevention in the Alabama Black Belt, we designed a multilevel church-based intervention using peer support. This study is 1 of the 5 randomized trials that comprise the RESTORE (addressing social determinants to prevent hypertension) network. Funded in 2021 by the American Heart Association as part of a pledge to address SDOH and improve the equitable health of all 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. Each trial is testing novel strategies to implement evidence-based interventions informed by community stakeholders, addressing multiple SDoH and using the reach, effectiveness, adoption, implementation, and maintenance (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 article describes the design of the equity in prevention and progression of hypertension by addressing barriers to nutrition and physical activity (EPIPHANY) study.

METHODS

Brief study overview

The EPIPHANY study is a cluster randomized controlled trial conducted in Black churches located in the Black Belt region of Alabama to test the effectiveness of online education modules combined with individual-level coaching and community-level peer support vs. online education modules alone on the prevention and progression of hypertension. The conceptual framework for the study is shown in Figure 1. Guided by the RE-AIM framework,¹³ we will use a type 1 hybrid design with effectiveness,¹⁴ defined as the change in BP, as the primary outcome, and measures of reach, adoption, implementation, and maintenance as secondary outcomes.

Recruitment

We are enrolling 20 churches located in the Alabama Black Belt. From each church, we will recruit 24 Black individuals, 19 years of age, and older with elevated or stage 1 hypertension who are not taking and not recommended antihypertensive medication according to the 2017 American College of Cardiology/ American Heart Association BP guideline (Figure 2).¹⁵ People who are <19 years of age, pregnant, have medical conditions with limited life expectancy, have no access to a telephone, expect to move out of the area in the next 24 months, are not community-dwelling, or cannot speak English are excluded (Table 1). Non-English speakers are very rare in these communities.

Churches in the Black Belt are being identified and approached with help from our community partner, the Rural Alabama Prevention Center (RAPC). RAPC is a 501c3 nonprofit Corporation that received funding from the US Department of Health and Human Services, health resources and services administration the Delta States Rural Development Network Grant Program in 2016 to implement health initiatives in churches located within 18 Alabama counties comprising the Alabama Black Belt. Once a church has been identified, a readiness assessment is conducted with each point of contact or pastor to determine the church's overall readiness to begin the program. This assessment is based on their staff readiness, health fair availability, and participation in previous projects. According to their response, a welcome meeting is scheduled with the point of contact and pastor to present the project's expectations, roles, and commitments. Each church agrees to select a church champion who will serve as the point of contact for all communication regarding EPIPHANY and encourage their fellow church members to make the project a success. A non-binding Letter of Agreement is issued to the pastor or the appropriate church official detailing the agreement with RAPC and connection health.

After churches are enrolled in EPIPHANY and randomized, health fairs that provide BP screening, and education on hypertension-related health behaviors are held at each church. Individuals whose BP levels meet eligibility criteria are informed of the study. Those who express interest in participating are given a brief screener to identify other potential exclusion criteria. Those who are eligible and remain interested are invited to participate and complete informed consent. Afterward, they are encouraged to participate in the education sessions available during the health fair. The study began enrollment in August 2022. The expected duration of the study is approximately 4 years.

PROCEDURES

BP measurement

At the time of enrollment, we measure each potential participant's BP using their non-dominant arm and an Omron 907-XL device 3 times following the American Heart Association protocol. Using the mean of the 3 measurements, if systolic BP (SBP) is between 120 to 139 mm Hg or diastolic BP (DBP) is 80 to 89 mm Hg, the participant was screened for the remaining eligibility criteria.

Other covariates

Interviewer-administered questionnaires are being completed to assess each participant's sociodemographic characteristics including age, race/ethnicity, sex, education level, income,





CC: Community Coordinator; BP: blood pressure; RE-AIM, RE-AIM: Reach, Effectiveness, Adoption, Implementation, Maintenance Framework

Figure 1. Conceptual framework for the EPIPHANY study.

Table 1. Inclusion and exclusion criteria for the EPIPHANYstudy

Inclusion criteria

1.≥19 years of age.

2.Have a mean systolic blood pressure between 120 to 139 mm Hg or diastolic blood pressure is 80 to 89 mm Hg based on three consecutive blood pressure readings conducted during an in-person screening.** 3.Self-identify as Black or African American

- Exclusion criteria
- 1.Mean systolic blood pressure ≥140 mm Hg, or mean diastolic blood pressure ≥90 mm Hg.
- 2.Currently taking antihypertensive medication.
- 3.Self-reported history of hypertension outside of pregnancy.
- 4.Known pregnancy.
- 5.Self-reported history of cardiovascular disease.

6.Age ≥65 years or self-reported history of chronic kidney disease, or diabetes, if systolic blood pressure ≥130 mm Hg or diastolic blood pressure ≥80.

- 7.Planning to move out of the county within the next 24 months. 8.Not having a cellular phone or landline.
- 9.Inability to speak English.

medical history, current smoking status, physical activity level, alcohol consumption, stress, social support, sleep quality and individual-level SDOH (Table 2). Height and weight are measured during study visit 1 following a standard protocol.

STUDY INTERVENTION

For this study, we adopted a peer coaching intervention previously shown to be effective for reducing BP among African Americans with uncontrolled hypertension aged 19–65 years living in the Black Belt.¹⁶ The peer coaching intervention is a one-on-one, telephone-delivered, structured program that is highly customizable to the individual. Its main goals are to assist participants with goal setting related to healthy eating and physical activity, to identify SDOH barriers to healthy lifestyles and help participants brainstorm solutions, to link them with local resources, to provide emotional support, and to link



Figure 2. Study design for the EPIPHANY study.

the participant to physician care when indicated. Its theoretical underpinnings are grounded in the self-determination theory which posits that when behaviors are autonomously motivated, individuals are more likely to maintain the behaviors over the long term.¹⁷ To implement the peer coach intervention we partnered with connection health, a local 501c3 that trains and deploys community health workers in central and south Alabama. Peer coaches are recruited from the research team's past studies or from the community; they receive at least 24 hours of structured training over approximately 1 month. The intervention itself includes an intensive intervention phase of biweekly peer support calls for 6 months, each focused on specific topics (Table 3), followed by 6 months of monthly maintenance calls.

Each coaching session requires the participant to watch an educational video, which is used as the basis for discussion

 Table 2.
 Survey measures being collected by self-administered questionnaires in the EPIPHANY study

Survey measures	Number of items	Description		
Eligibility screening form		Demographics (race/ethnicity, sex, and age) and medical history including age, blood pressure measurements, cardiovascular disease history, medications, and access to cellular phone or landline.		
Social determinants of health Diet	22	Assesses social needs including food insecurity, housing instability, and financial strain.		
Block sodium screener		Assesses dietary sodium intake.		
Block fruit and vegetable		Assesses dietary fruit and vegetable intake.		
Physical activity: SIMPAO	5	Assesses physical activity and sedentary behavior.		
Depression: CES-D	20	Assesses symptoms associated with depression, including restless sleep, loss of appetite, hopelessness, and loneliness.		
Perceived stress scale	4	Assesses stress perception levels over the past month.		
Functional social support	8	Assesses one's perspective of their social network.		
Krieger's discrimination scale	9	Assesses experiences of discrimination in various settings.		
Quality of life: SF-12	12	Assesses general health status including physical functioning, vitality, social functioning, and mental health.		
Treatment self-regulation				
Diet	15	Assesses the level of autonomous self-regulation and motivations for changing dietary behaviors.		
Exercise	15	Assesses the level of autonomous self-regulation and motivations for changing exercise behaviors.		
Perceived competence scale				
Diet	4	Assesses one's feelings of competence about engaging in dietary behavior change.		
Exercise Literacy	4	Assesses one's feelings of competence about engaging in exercise behavior change.		
Single-item literacy screener	1	Assesses the need to have someone help read instructions, pamphlets, or other written material from a doctor or pharmacy.		
literacy scalE	8	Assesses understanding, comfort, and perceived skills at finding, assessing, and using electronic health information to address health problems.		

during the telephone session. At each session, the participant and peer coach review progress toward personalized goals to improve BP self-management. Coaches meet monthly either in person or by phone with community-based coordinators to share experiences, review their progress with each participant, offer opportunities for protocol reinforcement, and troubleshoot challenges. Coaches are compensated \$300 for completing training, \$25 for each participant session, \$25 for attending monthly meetings with the community coordinator, and receive a \$300 phone/internet stipend.

Community level intervention

On the community level, churches randomized to the intervention receive training from 2 to 3 church members to serve as church champions (i.e., peer health advocates). Using an adapted version of the body and soul intervention, body and soul plus, church champions deliver education and support for lifestyle modification to the church and community members on an ongoing basis.¹⁸ Body and soul is a culturally relevant, evidence-based intervention, and dietary program developed to increase fruit and vegetable intake, designed with and for African American churches. The RAPC has delivered the original body and soul (minus peer coaching) in churches in the Black Belt since 2016. For body and soul plus, participants were given educational resources on physical activity and the impact of SDOH on cardiovascular outcomes in rural areas. Group activities are included to have church champions identify local resources that can be cataloged for the local community. Churches also receive \$1,600 to develop unique programs to address food access and/or barriers to physical activity for their congregation and church community. Church randomized to the control condition will receive the community-level intervention after 12 months of participation in the study (delayed intervention).

Control condition

Access to biweekly online education sessions alone is the comparator for the study. Sessions are developed and hosted by our community partner, connection health, and include cooking demonstrations, physical activity sessions, and webinars on stress management, sleep hygiene, and other relevant health topics. The classes occur live on Facebook and then are archived and accessible to participants through Youtube. All participants have access to education regardless of randomization status.

STATISTICAL ANALYSIS

Randomization

Randomization will occur at the individual church level. Each church will be randomly assigned to the intervention or control group using R programming language employing random block sizes of 2 and 4.

Statistical analyses

Statistical analyses will be conducted blinded to randomization assignment using the latest release of R. Assumptions for all statistical inferential tests and modeling will be examined including

Table 3. Topics for EPIPHANY peer coaching sessions
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Session	Торіс	Content
1: Introduction	Introduction to the program	Introduce EPIPHANY program and explain the session schedule. Relationship building between peer coach and participant Connecting the goal of the project to motivation for engagement.
2: Blood pressure	How to take your blood	Review home blood pressure monitoring protocol, the importance of self- measured blood pressure and set goals for monitoring
3: What is Hypertension?	How to manage blood pressure at home	Explains what hypertension is Life's Simple 7 and hypertension prevent Review blood pressure numbers and hypertension definition
4: Healthy Eating Strategies: Part 1	Education on salt intake and its impact on blood pressure	Explains how to prod pressure can be controlled (limiting salt intake/eating healthy foods) and the benefits of having a normal blood pressure. Practice tracking food intake
5: Healthy Eating Strategies: Part 2	Simple 7 tips to eat healthily	Set SMART goals for reducing salt and brainstorm solutions to barriers. 7 simple ways to plan for good nutrition (plan one day at a time, choose foods high in fiber, low in cholesterol, etc., avoid foods/drinks with added sugar, include fish rich with omega-3s, prepare lean meat with no extra saturated/ trans fats, and cut back on salt intake) Introduction to the sections of myplate.gov Provides strategies for grocery shopping. Brainstorming solutions to barriers.
6: Healthy Eating Strategies: Part 3	At home recipes	Provides benefits and the importance of planning meals and following recipes.
7: Physical activity: Part 1	Life's simple 7: get active	Provides the benefits of physical activity and explains exercise recommendations for adults. Discusses plans for becoming more physically active Introduction to exercise/physical activity tracking. Discusses fitting physical activity into your schedule
8: Physical activity: Part 2	Physical activity guidelines	Provides guidelines for muscle-strengthening activities and definitions of moderate/vigorous physical activity Implements muscle-strengthening activities into exercise tracking. Review SMART goals and barriers.
9: Stress management	Coping with stress	Healthy and unhealthy coping strategies. Alcohol and smoking, stress eating, and benefits of exercise. Health effects of chronic stress include increased BP. Awareness of stress levels and identifying sources of stress. Deep breathing techniques and relaxation. Set SMART goals for reducing stress and barriers.
10: Social Connections	Social connections matter to your health	Discusses the importance of social connections and support. Identifying sources of support. Family/friend support and overcoming barriers to behavior change.
11: Mental and physical health	Connection between mental and physical health	Discuss the importance of mental health; benefits vs. Barriers. Set SMART goals for mental health improvement.
12: Recap session	Social determinants of health and Community resources;	Accessing community resources for healthy behaviors and overcoming barriers. Identifying local health resources. Final recap of the program.
13-Maintenance	Monthly check-ins	Review goals and discuss solutions to barriers.

Abbreviations: EPIPHANY, equity in prevention and progression of hypertension by addressing barriers to Nutrition and physical activity; SMART, Specific, measurable, achievable, relevant, time-bound.

normality of residuals and homogeneity of variance across treatment groups and over time. If assumptions are not met, transformations will be investigated (e.g., square root or natural log). 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 conduct main analyses using multiple imputation and sensitivity analyses among those with complete data. All analyses will be intention-to-treat, regardless of intervention fidelity and intensity of the intervention received. Statistical significance will use an alpha of 0.05.

To assess if the intervention changes BP, we will construct separate longitudinal models for SBP and DBP using values measured at baseline and 6 and 12 months following baseline. The independent variables will include follow-up time, randomization assignment of the church, and their interaction. Our primary target of inference will be the time by treatment interaction, as this will measure the impact of the intervention. If the effect of the intervention is not linear over follow-up time, we will use a time-averaged model. In a secondary analysis, we will test if the intervention changes SBP and DBP at 6 and 12 months, separately. We will calculate the cumulative incidence of hypertension in each randomization group and use discrete-time survival analysis with logistic regression and a cumulative log-log link to estimate the hazard ratio for incident hypertension comparing the intervention vs. control.

We will use Glasgow's RE-AIM framework to guide our assessment of the intervention's implementation at the individual and community level. Table 4 describes RE-AIM indicators used to evaluate implementation. Effectiveness (clinical) is assessed as described above. To assess reach, we are tracking the number of

Dimension	Indicator	Definition
Reach	Enrollment in the study	% enrolled of those approached & eligible.
Effectiveness	Online cooking & physical activity session participation Peer support call participation	% of participants attending sessions (total & by modality). % of participants completing individual contacts.
Adoption	Adoption by churches	% of churches enrolled of those approached. % of wellness programs initiated by enrolled churches.
	Adoption by CC	% of CCs invited that agree to be trained % of CCs that complete training/drop out
	Adoption by peer coaches	% of peer coaches invited that agree to be trained. % of peer coaches that complete training/drop out.
Implementation		
Setting level	Sessions & telephone contacts	# of online sessions & individual contacts delivered.
	Peer support call duration	Start/end time of each session/contact
	Protocol modifications	#, type of changes made to peer support protocol.
	Total program costs	Cost of each program component & overall costs.
Individual level	Goal setting	#, % setting SMART goals (total & by topic).
	Self-monitoring of diet & physical activity, BP Individual participant costs	#, % tracking diet, physical activity, BP. Cost of phone minutes, internet, etc.
Maintenance	BP Self-monitoring of weight, diet, Physical activity CC activities Church wellness program	Change in BP level between 12 and 24 months. Maintenance of self-monitoring behaviors at 24 months. #, % CCs still leading activities at 24 months. #, % of programs sustained at 24 months.

Table 4. RE-AIM indicators and definitions

Abbreviations: BP, blood pressure; CC, Church champion; SMART, specific, measurable, achievable, relevant, time-bound.

individuals approached and the number that agreed or declined to participate. We are also collecting information about reasons why people declined to participate. Adoption is being ascertained by estimating the proportion of churches and church champions willing to participate and deliver the intervention. Implementation is being assessed at 12 months post-intervention; at the church level we are assessing adherence to the protocol, dose of the program delivered, quality of program delivery, and protocol modifications and at the individual level we are assessing participants' use of goal setting and self-monitoring. Maintenance of BP levels is being ascertained by modeling the change in SBP and DBP from 12 to 24 months following baseline among participants randomized to the intervention using linear mixed models.

Cost-effectiveness

The validated SF-12 instrument is being used to assess global health-related quality of life at the baseline and final visits of all participants. Intervention cost information will be gathered through structured interviews of study staff, financial records, and direct observation (staff and participant time 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 stage 2 case prevented) and project longer-term cost-effectiveness (cost per quality-adjusted life-years gained at 10 years and over the remaining lifetime) using the hybrid BP Control-CVD Policy Model.

Study outcomes

The primary study outcome is a change in SBP at 6 and 12 months. Secondary outcomes include the change in DBP and the cumulative incidence of hypertension at 6 and 12 months. With a sample size of 480 participants (assuming a drop-out rate of 15%), we will have 88% statistical power to detect a difference in SBP of 4 mm Hg among participants randomized to the EPIPHANY intervention compared to the control. A 4 mm Hg reduction in SBP was chosen as it reflects ~50% of the benefit of

lifestyle interventions observed in efficacy trials. 19,20 For secondary outcomes, we will have 90% power to detect a difference in DBP of 3 mm Hg.

DISCUSSION

The EPIPHANY trial is contributing to the RESTORE Network and the mission of the American Heart Association to increase health equity by testing a multilevel intervention designed to prevent the development of hypertension among rural, Black adults living in the Alabama Black Belt. The study design combines existing approaches, pairing a peer coaching model with church-based interventions to help create solutions to address barriers to healthy behaviors. The trial is devised to have adequate power to test its main hypotheses and should provide valuable data on the feasibility, scalability, and sustainability of church-based, peer-support interventions in rural, Black communities.

For this study, we conceptualized the intervention as having 2 levels. On the community level, we designed a structural intervention focused on mitigating unique structural barriers to engaging in health behaviors in the Alabama Black Belt, such as long distances to grocery stores^{11,21} and limited availability of public recreation facilities.^{21,22} In the EPIPHANY trial, leadership committees within each church are empowered to develop a project (e.g., community food pantry, farmer's market, Zumba instruction, and small church gym) aimed at overcoming structural barriers to healthy behaviors. Alabama ranks 1st in the United States in the percentage of the population that identifies as religious and church attendance is higher than the nation's average,²³ making churches an ideal venue for conducting a community-based intervention in the Black Belt. Utilizing the role of churches as pillars of trust, definers of social acceptability, and influencers of behaviors, church-based interventions have been successful in reducing BP in Black congregants in prior studies.²⁴ Leveraging churches in the EPIPHANY trial aids in shifting the sociocultural environment and community attitudes about health behaviors and strengthens the affordability and sustainability of the community-level strategy.²⁵

On the individual level, the EPIPHANY trial is grounded in a relationship-focused peer support intervention. As is typical with peer coaching, lay peer coaches from the Black Belt community, who are trusted and know their communities' needs and strengths, are trained by EPIPHANY community partners to develop a supportive relationship to assist church participants with optimizing self-management and overcoming barriers to health behaviors. Working with a peer coach enables participants to have discussions with someone they feel understands them and their community, which can assist with recommendations for self-management. A 2019 review of 29 studies on the effectiveness of peer coaches to improve BP among individuals with hypertension suggested interventions can lower SBP by a mean of 8 mm Hg.²⁶ However, fewer studies have rigorously evaluated the use of peer coaching to prevent the development of hypertension, or been implemented in rural communities.²⁷ This study will not only provide data on the potential effectiveness of peer coaching on hypertension prevention in rural settings but will also provide important insights into factors related to adoption, implementation, and sustainability.

The design of this implementation trial was guided by an established implementation science framework, the RE-AIM framework.¹³ We are collecting process data that will allow other researchers, community groups, and churches to examine the suitability and feasibility of implementing these interventions in their areas, should the trial demonstrate effectiveness. The intervention being evaluated has potential for wide scalability in the Black Belt region, in part because we partnered with existing community organizations to recruit churches and coordinate peer coaching activities, creating capacity to sustain and grow such programs in the communities where the intervention is being tested. A challenge for long-term sustainability will be the financial support for peer coaching programs and church-based resources for overcoming barriers. The work of the cost-effective core within the RESTORE Network and the engagement of community leaders in our community advisory boards will allow us to facilitate discussions on strategies to enhance financial sustainability.

High rates of hypertension combined with high rates of poverty in the rural south, contribute to health disparities with Black adults experiencing higher CVD rates, and a shorter life expectancy than seen in other US regions. A multilevel, churchbased intervention anchored by peer support has the potential to concurrently address barriers to healthy behaviors and reduce the risk for hypertension. The EPIPHANY trial has the potential to impact health equity through the primary and primordial prevention of hypertension in a high-risk, underserved population.

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DISCLOSURE

The authors declared no conflict of interest.

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