Implementation Science

STUDY PROTOCOL

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Community intervention to reduce cardiovascular disease in Chicago (CIRCL-Chicago): protocol for a type 3 hybrid effectiveness-implementation study using a parallel cluster-randomized trial design

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Abstract

Background Hypertension affects nearly half of adults in the U.S., with African American and Black (AA/B) adults experiencing some of the highest rates domestically and globally. Despite improvements in blood pressure control in the general population, rates of control among AA/B adults have stagnated, contributing to significant health disparities in the prevalence of hypertension and its long-term health impacts. Systemic barriers, including poverty and historically earned distrust in healthcare, hinder patient and clinician adherence to best practices for hypertension management. Community-based interventions, particularly those involving faith-based organizations, show promise in improving blood pressure control among AA/B adults.

Methods The CIRCL-Chicago Implementation Research Center will test the effectiveness of a community-adapted hypertension control program, a "bundled" intervention developed by and tested in the Kaiser Permanente system, in South Side Chicago community health centers. A key partner for this trial, the Total Resource Community Development Organization, isa faith-based community outreach hub networked with faith-based organizations throughout Chicago's South Side community. The study employs a type 3 hybrid effectiveness-implementation approach with a parallel cluster-randomized trial. Sixteen clinics will be randomized to implement a community-adapted Kaiser bundle with or without practice facilitation. We will recruit adults who live, work, or practice their faith in Chicago's South Side community to populate a community-based hypertension registry (target n = 5,760 participants). The primary implementation outcome is the reach of the intervention, measured by the proportion of eligible patients in the registry who receive the adapted Kaiser bundle. Secondary outcomes include blood pressure control rates, assessed at 12 months post-enrollment. The study will use community-engaged adaptation, practice facilitation, and education and training strategies to support implementation.

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Discussion The CIRCL-Chicago study aims to address cardiovascular health disparities by integrating clinical and community-based approaches to hypertension management. By leveraging trusted community settings and engaging local partners, the study seeks to enhance the reach and effectiveness of evidence-based hypertension interventions. The findings could inform scalable models for hypertension control in diverse urban communities, potentially reducing health disparities for AA/B adults.

Trial registration Clinicaltrials.gov NCT04755153 on 24 August 2023, https://www.centerwatch.com/clinical-trials/listings/NCT04755153/community-intervention-to-reduce-cardiovascular-disease-in-chicago

Contributions to the literature

- This study will be the first to evaluate the implementation of a community-adapted version of a multilevel, evidence-based hypertension control program (the Kaiser Bundle adapted for the local community), including an added component to address health-related social risks and a novel partnered delivery strategy
- The trial will test the impact of tailored practice facilitation on the reach of the adapted Kaiser bundle of hypertension interventions in an underserved community with marked cardiovascular health disparities
- This study has the potential to improve identification, diagnosis, and control of blood pressure among under-resourced communities via novel partnerships between healthcare and faith-based organizations—trusted voices in African American/Black communities that could be instrumental for health equity

Background

Nearly half of adults in the United States have hypertension, and only 43.7% have their blood pressure (BP) under control [1]. African American and Black (AA/B) adults have rates of hypertension that are among the highest in the world [2]. The difference in BP control rate between non-Hispanic White (55.7%) and AA/B (48.5%) populations contributes to the 5.5-year difference in life expectancy between AA and White individuals [3, 4] and the AA/B 30-year all-cause mortality rate being nearly double that of White individuals [5]. Evidence suggests that lower adherence to medications and lifestyle recommendations (e.g., the Dietary Approaches to Stop Hypertension [DASH] diet) leads to disparities in BP control for AA/B compared to White adults with hypertension [6, 7]. Poor adherence is driven by systemic barriers including poverty, housing insecurity, and food apartheid [8], as well as low levels of trust in the healthcare system [9], among other factors [10]. The optimal intervention to control BP in AA/B individuals would bring tailored and effective interventions to community settings delivered by trusted community members [11, 12].

Between 2001 and 2009, Kaiser Permanente Northern California implemented and evaluated a large-scale hypertension program [13]. The "Kaiser bundle" included: a health system-wide hypertension registry, BP control reports, an evidence-based BP control guideline, medical assistant follow-up visits for BP management (under physician supervision), and promotion of single-pill combination therapy. Results for the registry study of over 600,000 patients showed that one-year BP control rates increased from 44 to 80% [13].

Despite its effectiveness in the Kaiser Permanente system, Wong et al. noted that "skepticism abounds across the U.S. health care system regarding transfer of successful practices to other organizations. Many believe that successful practices are inherently bounded by their own organization's parameters and culture" [14]. Thus, in 2008, safety net clinics in Northern California adapted the Kaiser bundle for a more diverse population than the original study [14]. The essential components were kept; results demonstrated a significant but less robust effect on BP control rates (~6% improvement) than the original study. While this study demonstrated the capacity to successfully adapt and transfer the Kaiser bundle, it remained centered within healthcare facilities. For people living in lower-resourced communities, social and structural inequities are greater drivers of health disparities than healthcare itself [15–17].

Culturally adapted interventions embedded in *trusted community settings* have the potential to increase adherence to hypertension recommendations in AA/B adults. For example, AA/B churches have traditionally served as trusted service providers in AA communities [18, 19]. AA individuals have the highest religious commitment and religious social support among all races and ethnicities in the nation [20, 21]—87% of AA/B adults report a formal religious affiliation and 53% attend weekly religious services [22].

Accordingly, several lifestyle interventions targeting cardiovascular disease risk factors have been conducted in AA/B churches [21, 23–26]. However, to our knowledge, the FAITH study [26] and CHERISH study

[27] (ongoing) are the only randomized trials to test the effectiveness of a church-based lifestyle intervention for uncontrolled BP. The FAITH intervention, delivered by church members trained as Lay Health Advisors, consisted of 11 weekly group-based education and skill-building sessions. This was followed by three monthly one-on-one motivational sessions focused on following a DASH-style diet, increasing physical activity, and reducing stress. At 6 months, the intervention group showed a statistically significant net decrease in systolic BP relative to the control group (-5.8 mmHg). At nine months, the difference (-5.2 mmHg) was no longer statistically significant. Hence, church-based interventions have potential to improve BP, but a more potent intervention that integrates lifestyle education with clinical hypertension management may be necessary to achieve a sustained, clinically significant benefit of -10 mmHg in systolic BP [28].

One such integrated approach is illustrated by a cluster-randomized trial of a BP intervention for AA/B men that was delivered by pharmacists in 52 men's barbershops in Los Angeles [29]. During regular barbershop visits, participants met with a pharmacist who prescribed and monitored a drug-intensification regimen and provided regular feedback to the participant's primary healthcare provider. Results showed a mean 6-month reduction in systolic BP of 27.0 mmHg in the intervention group versus 9.3 mmHg in the control group. However, it is impractical to staff pharmacists permanently within barbershops. Our proposal to tightly link a community-based intervention in coordination with clinic-based BP management has potential to achieve similarly powerful reductions in BP, reach a wider population of AA/B individuals (not just males), and be more acceptable, cost-effective, and sustainable.

Too often, best available interventions are applied inequitably across settings and populations and further exacerbate health disparities [30]. This "scientific inequity" [31] begins with the underrepresentation of historically disadvantaged populations in intervention research [32] and persists into wide-scale implementation across settings and systems, where innovations can be slow in reaching or responding to the needs of communities experiencing avoidable health disparities [33, 34]. Cross-sector partnerships cultivated through community-engaged implementation research methods can help underserved communities implement and sustain evidence-based interventions [35]. These partnerships seek to create an equitable distribution of power and resources and arrive at a shared research agenda built on trust, perceived benefit from the research, and researchers' ongoing commitment to the community's priorities [36].

DECIPHeR alliance

The National Heart, Lung, and Blood Institute of the U.S. National Institutes of Health (NIH) convened a workshop of experts in 2017 to develop a roadmap for community-engaged implementation research for cardiovascular health disparities [37]. This workshop led to approval of funding to establish the Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Risk (DECIPHeR) Alliance. The Alliance comprises seven Implementation Research Centers (UG3/UH3 funding mechanism) and a research coordinating center (U24) [38].

CIRCL-Chicago implementation research center

The *Community Intervention to Reduce CardiovascuLar Disease in Chicago* (CIRCL-Chicago) Implementation Research Center, co-directed by multiple principal investigators Kho, Smith, and Davis, is a partnership among academic research institutions, community health center (CHC) networks, Total Resource Community Development Organization (TRCDO) (a faith-based community outreach hub), and national advisory groups. TRCDO was established as a 501(c)3 entity to assist at-risk families in need of immediate wraparound support services. In 2013, Pastors for Patient-Centered Outcomes Research (Pastors4PCOR) joined TRCDO's service roster, contributing expertise and research engagement support to local FBOs. Pastors4PCOR's mission is to "inform, inspire, and engage congregations in research through partnership." Since its inception in 2015, Pastors4PCOR has engaged and trained 125 Community Members, 59 Research Ministry Ambassadors (RMAs) (including in CITI Human Subjects Research), and 32 RMA Trainers (for spread and sustainment), representing more than 55 FBOs. Popular activities include community-based Institutional Review Board (IRB) training and a faith-based community health assessment of health priorities and factors with community members [39]. In 2016 and 2018, Pastors4PCOR administered a 10-item community health assessment to FBOs ranging in size from 500 to 2,000 in Chicago and collected 836 surveys from residents living in 12 ZIP codes. BP was the highest-rated health priority in both surveys—the pandemic further exacerbated concerns [11].

CIRCL-Chicago will test a package of implementation strategies for the community-adapted Kaiser bundle [11] versus the package plus practice facilitation (PF)—a strategy aimed at assisting primary care practices with developing capacity for sustained implementation of evidence-based interventions and practice changes [40]—in South Side CHCs. Our specific aims are presented in Table 1. Although the literature is limited, practice facilitation has demonstrated modest impacts on reach

Table 1 Specific aims

Aim 1: Test the impact of practice facilitation on reach of a community-adapted Kaiser bundle
Our primary implementation aim is to compare the reach of the community-adapted Kaiser bundle (i.e., the proportion of patients within a CHC who receive the Kaiser bundle) between the two arms (PF vs. non-PF) over the 24-month implementation period. *Hypothesis: CHC clinics assigned to receive PF will provide more patients with Kaiser bundle intervention components (reach) compared to the non-PF clinics*
Aim 2: Test the impact of practice facilitation on blood pressure control
Our health-related effectiveness aim is to compare the proportion of participants with controlled BP between the two arms (PF vs. non-PF) at 12 months (after each participant's study enrollment date). *Hypothesis: Participants receiving care in PF clinics arm will have greater BP control compared to those receiving care in the non-PF clinics because of greater implementation success resulting from PF*
Aim 3: Convene community partners in ongoing, prospective adaptation of the implementation
Extending outward from our core coalition, we will engage community leaders and patients in the South Side of Chicago in a prospective, data-driven, community-engaged adaptation of the way in which the Kaiser bundle is implemented to maximize effectiveness and alignment with local community preferences, needs, and resources [see 11, 42 for results of this work thus far]. *Hypothesis: Community-engaged adaptation will improve implementation and sustainability*
Aim 4: Disseminate findings internally to community partners and externally through creation of community implementation toolkits
In addition to academic dissemination, we will create community implementation toolkits designed to provide a step-by-step guide with resources and references for continual, community-driven adaptation; coordinated intervention between CHCs and FBOs; and the use of PF for hypertension management implementation. We will also coordinate with partners to present to their internal leadership, medical providers and other community groups who can take the results and scale them within their organizations

Legend: *BP* blood pressure, *CHC* community health center, *FBO* faith-based organization, *PF* practice facilitation

of the intervention (primary outcome) for a host of primary care–delivered interventions [41]. Our study design underwent extensive community review and incorporated the perspectives of various partners and interested parties, as well as input from NIH scientists and other grantees in the DECIPHeR Alliance through its various subcommittees. This adaptation process is described in two published articles [11, 42].

Methods/design

Models and frameworks

CIRCL-Chicago will use EPIS (Exploration, Preparation, Implementation, and Sustainment) as the process model [43]. The Dynamic Adaptation Process (DAP) model [44], designed for use in conjunction with EPIS, will be used to adapt the Kaiser bundle and implementation strategies. Assessment and characterization of context will be guided by the Crosswalk of IMplementation models and frameworks to advance health Equity (IM4Equity), a new framework developed by the DECIPHeR Alliance to better capture the structural, societal, and sociopolitical drivers of health disparities as they pertain to implementation of health interventions to achieve health equity [45]. RE-AIM is the evaluation framework [46]. The Implementation Research Logic Model (IRLM) [47] will be used to bring these models and frameworks together. The CIRCL-Chicago IRLM was published in Smith et al. [42] following our UG3 phase work; a final IRLM will be published with the primary outcomes.

Setting

In 2018, the estimated rate of hypertension was 27.7% of the adult population in Chicago [48]. Hypertension rates in Chicago's South Side community are significantly higher, at 36.9% on average for AA/B adults. CIRCL-Chicago will bring together two CHCs with clinic locations in the South Side community— Access Community Health Network (ACCESS), a federally qualified health center, will contribute 7 health centers (i.e., clinic locations) and Advocate Aurora Atrium Health will contribute 9 ($n=16$ total clinics)—all of which will implement the adapted Kaiser bundle and half will receive PF. During the UG3 phase of the project, the team worked closely with community members and partners to design a community-oriented model for delivery of the Kaiser bundle in coordination with FBOs and trusted community organizations, chiefly TRCDO. The Pastors4PCOR program, which is the conduit between TRCDO and its partner FBOs, trains RMAs in human subject research to recruit and consent participants, collect data, and perform BP measurements. Beyond Pastors4PCOR, TRCDO is positioned to provide services for identified health-related social risk (HRSR) identified in study assessments. TRCDO operates a food pantry and assists community members with housing and utility assistance, helps members obtain health insurance, among other services. More information about this coordinated partnership and how it was developed in the UG3 phase of this study is available in Philbin et al. [11].

Clinical intervention

The clinical intervention is an adaptation of the Kaiser bundle to match the needs of a predominantly AA/B community with significant cardiovascular disease disparities and for implementation by CHCs in coordination with FBOs. Details on adaptions to the Kaiser bundle made during the UG3 phase of the study are presented in a Table 2. All protocols are consistent with the 2017 Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults [49].The components of the intervention, and how they will be applied in our study, are as follows.

1. Creating and maintaining a registry of adults with hypertension. Our community-based registry is a HIPAA-compliant data infrastructure called the Eureka platform (https://info.eurekaplatform.org/our-services/). A unique Northwestern Eureka instance was developed to e-consent patients, gather study eligibility information, and then track study consent, participation, and follow-up.
2. Developing and distributing BP control reports. Consistent with the Kaiser bundle, clinic-level reports about BP control will be distributed on a quarterly basis to practice managers and BP Champions in the CHCs.
3. Developing and distributing a standardized BP measurement and treatment protocol. In collaboration with community partners, our team will develop and distribute a simplified BP measurement protocol for use by CHCs and RMAs. This protocol will be used in training and form the basis of fidelity indicator identification from EHR data.
4. BP follow-up visits. These visits will be completed with medical assistants or trained research coordinators (under physician supervision) at CHCs. BP follow-up readings may also be completed by RMAs in the community.
5. Single-pill combination therapy. Clinicians will be encouraged to prescribe single-pill combination therapy for appropriate patients. We will provide educational seminars in the community about antihypertensive medication.
6. Community resources. A new component of the Kaiser bundle, community members will be queried for HRSRs and referred to appropriate community resources, including TRCDO.

Participants

There are two samples in CIRCL-Chicago: 1) study participants and 2) CHC staff.

Study Participants

To test the effectiveness of the adapted Kaiser bundle on BP control, participants will be recruited into the hypertension registry from the South Side Chicago community within engaged CHCs and by FBOs during the 12-month implementation period. Recruitment materials will be customized for these recruitment venues.

Recruitment through CHCs. We will recruit patients via blood pressure registries/EHR queries in participating clinics. Reports will identify adults who are 18–85 years old, have a documented in-person encounter, and a documented diagnosis of hypertension, and who do not have documented end-stage renal, dementia, or hospice care.

A study coordinator will perform outreach to identified individuals via telephone, email, mail, and/or in-person clinic visits. Participants may also be referred to the study by their clinician during clinic visits or by word-of-mouth. The potential participant will meet with a study coordinator to complete the informed consent process, including providing education about the study, answering any questions the patient may have, explaining the opt-out and withdrawal processes and obtaining baseline BP measurements.

Recruitment through FBOs. Recruitment in FBOs will be conducted by study coordinators and RMAs who completed the Pastors4PCOR training via health fairs, community outreach, and other local events. Participants will be determined to be eligible if they self-report having been told by a clinician that they have a diagnosis of hypertension. If a potential participant's baseline BP measurement is consistent with hypertension (i.e., $\geq 140/\geq 90$ mmHg), but the person does not have or cannot recall whether they have been diagnosed with hypertension, they will require diagnosis by a clinician—the study team will provide information to help the person connect with primary care if needed. The study team will follow up with the person up to four times to inquire about scheduling and completing a medical visit. If the person receives a diagnosis, they will be eligible. Although some participants enrolled via the FBOs will not receive care in a study CHC, they will nonetheless be enrolled, assessed, and followed with specific questions pertaining to receipt of medical care in non-study clinics.

CHC staff

CHC staff from the 16 clinics will be recruited to complete surveys and participate in focus groups concerning implementation. Invitations will be sent via email to all

Table 2 Adaptations to the Kaiser bundle prior to implementation

Component	Original Kaiser Bundle (Jaffe 2013)	Kaiser Bundle Adapted for FQHCs (Fontil 2018)	Kaiser Bundle Adapted for CIRCL-Chicago
Patient registry	Patients with hypertension were identified quarterly using outpatient diagnostic codes, pharmacy data and hospitalization records from health plan databases, and diagnoses were verified through chart review audits of random samples of identified members	Development of an internal hypertension patient registry to facilitate provider performance feedback and panel management outreach to schedule patients with uncontrolled HTN for BP visits	Hypertension registry shared between CHCs and FBOs, using the Eureka platform. Participants enrolled in registry after active consent; identified through health record queries in CHCs and at FBO sponsored community events
Hypertension control reports *(Performance reports?)*	Reports generated every 1–3 months for each medical center and distributed to their directors. Reports were also available for clinic leaders to generate when needed	Clinic-level reports, stratified by race, shared with clinic leaders monthly and available for clinic leaders to generate reports	Quarterly reports generated for each of the two CHCs and distributed to practice managers by the BP Champion and site PI. FBOs: Study-wide quarterly report focused on study enrollment and BP control
Evidence-based practice guideline	A four-step hypertension control algorithm was developed to aid clinicians	Partnered with nurse leaders to design a standardized BP measurement protocol	In collaboration with community partners, we will develop and distribute a simplified BP measurement protocol, per AHA guidelines, for use by CHCs, community health workers, and RMAs in FBOs
BP checks	Every 2–4 weeks, a medical assistant measured blood pressure and informed the primary care physician, who then directed treatment decisions and follow-up planning	BP check visits led by registered nurse and pharmacist staff	BP checks may be conducted by RMAs in non-healthcare settings and by nurses/medical assistants in the CHCs
Medication *(treatment)* guideline	Single-pill combination therapy (lisinopril-hydrochlorothiazide) incorporated into the regional guideline as being optional for initial treatment and recommended as a step two strategy	A simplified evidence-based treatment intensification protocol, modified to account for drug coverage and affordability, patient complexity, and clinical guidelines	We will develop and distribute a standardized treatment protocol, per AHA guidelines, for use by CHCs and community health workers focused on affordable single-pill combination therapies
Community resource referrals	Not specifically part of the bundle	Not specifically part of the bundle	Assessment of health-related social risks in Eureka; RMAs and project coordinators/CHC healthcare staff make and coordinate referrals to community-based resources for identified needs

eligible staff in the practice, including primary care clinicians, advanced practice providers, nurses, clinic support staff, and leaders (e.g., practice managers). In-person recruitment during staff meetings will also be used following email invitations. Surveys will be administered via REDCap at baseline and again at 6 and 24 months into implementation. Adapted versions of the Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of Intervention Measure measures [50] will be used to assess the components of the Kaiser bundle as well as implementation strategies. We will also administer the Change Process Capability Questionnaire [51] at baseline, and short forms validated by Smith et al. [52]of the Organizational Change Recipients' Beliefs Scale [53] and Implementation Leadership Scale [54]. Focus groups will be conducted at 6, 12, 18, and 24 months after beginning implementation of the adapted Kaiser bundle. Interview guides will be developed using key domains of the EPIS model and the IM4Equity framework [45]. Where allowable by their CHC, the staff participants will receive monetary compensation for surveys and focus groups as allowable.

Study procedures

Community members who consent will be enrolled in the study via the Eureka platform (i.e., community-based hypertension registry). Participants will undergo a BP measurement with a trained study coordinator or RMA using automated BP cuffs at baseline and 12 months post-enrollment. In the case of a hypertensive crisis (i.e., BP readings $\geq$ 180/$\geq$ 120 mmHg), the participant will be put in contact with the study cardiologist for assessment and a plan of action (e.g., urgent care/emergency department visit). Already established clinical workflows will be followed in medical settings. Participants will also be invited to complete study surveys (detailed below) via the Eureka platform at baseline, 4 months, 8 months, and 12 months post-enrollment. In the case of an identified HRSN, participants will be provided with a list of relevant local resources. Community participants will not receive compensation for BP measurement and surveys in Eureka.

Study design

CIRCL-Chicago is a Type 3 effectiveness-implementation hybrid study [55]. We will test the impact of PF, an evidence-based strategy, on the implementation of the adapted Kaiser bundle, compared to implementation without PF, in CHCs. We will employ a two-arm (Kaiser bundle with PF or Kaiser bundle without PF; 1:1 allocation) parallel cluster (clinic-level) randomized controlled trial, utilizing matching based on clinic size and the proportion of AA/B adults served annually to ensure a balanced distribution across arms. Figure 1 provides a modified version of the Consolidated Standards of Reporting Trials (CONSORT) diagram for cluster randomized trials [56]. Study condition cannot be masked for CHCs and the PF. A statistician will have access to randomization assignment to prepare reports for the Data Safety and Monitoring Board. All investigators, staff, and participants will be kept masked to outcome measurements and trial results until all analyses are final.

Implementation strategies

CIRCL-Chicago will use a "package" of implementation strategies headlined by community-engaged adaptation, PF, and education and training. Additional implementation strategies identified in our UG3 work are included in the study IRLM [57] that appears in Smith et al. [42].

Community-engaged adaptation

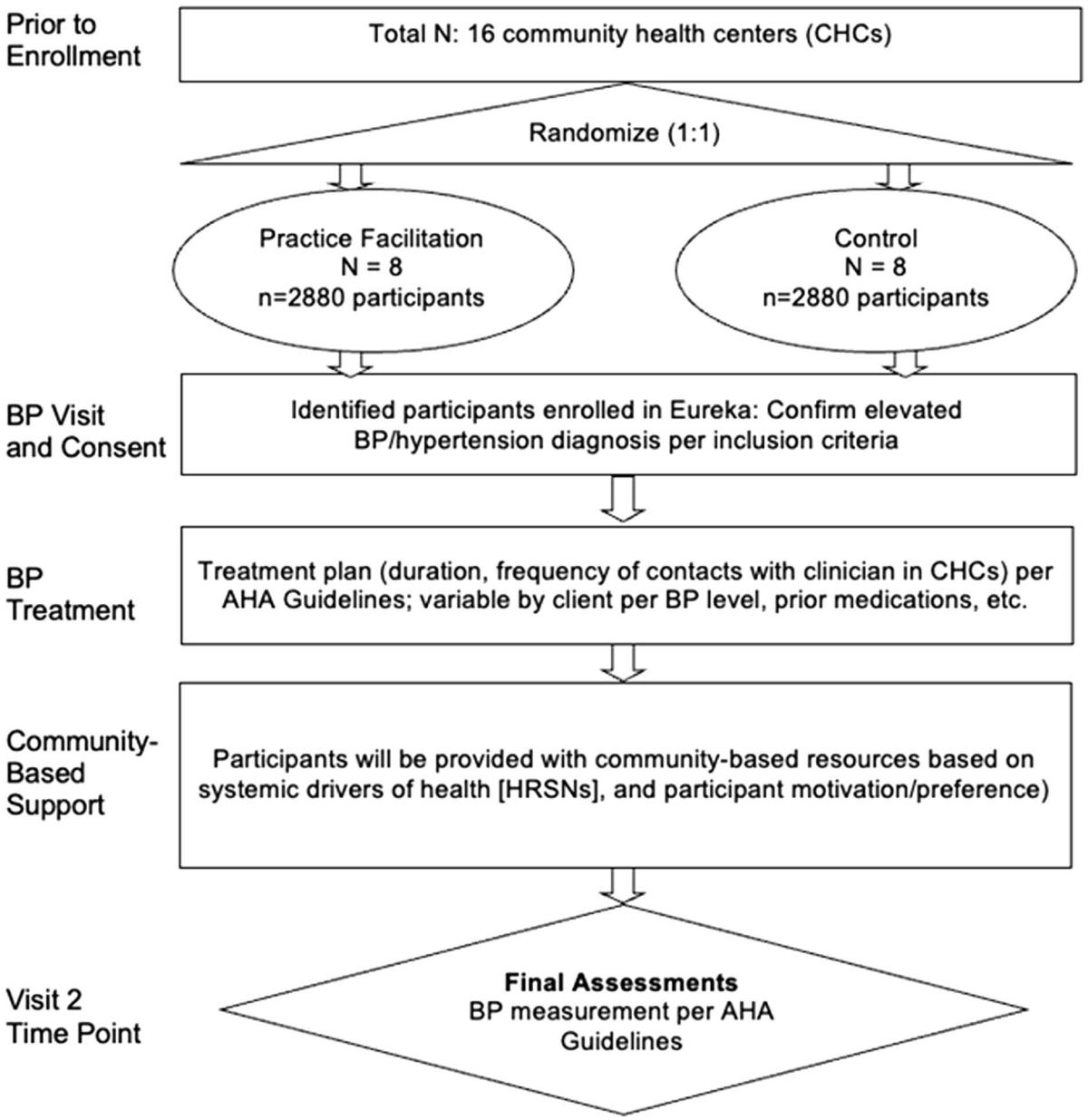
During implementation, we will follow the Dynamic Adaptation Process model [58] to engage community and implementation partners. This model is a prospective, data-driven approach involving (1) identifying core components of the Kaiser bundle and their adaptable characteristics, (2) developing guidance to implementers on allowable adaptations to maintain fidelity, (3) creating a system for monitoring fidelity during delivery, and (4) identifying organizational/delivery system adaptations. We will integrate community-based implementation research methods and principles [37] with the DAP to align our implementation to the local community context.

Practice facilitation

PF is a method to help practices implement evidence-based interventions [59], with demonstrated success in improving care across a range of common chronic diseases [41]. The CIRCL-Chicago PF team includes one experienced practice facilitator who will be responsible for working with "BP champions" at each CHC site to develop training materials to optimize approaches for educating practices on the implementation of the adapted Kaiser bundle. Components of PF are:

Practice Tailoring. Clinical workflows to support the Kaiser bundle will be designed in collaboration with CHCs. Our clinician and staff champions, together with the practice facilitator, will tailor intervention and data collection strategies to be feasible for most practices, given local resources.

Program Tools & Materials. The practice facilitator will use a set of resources and tools to support BP control, including educational materials to support core skills (e.g., motivational interviewing, workflow optimization), validated and evidence-based BP control



Legend. AHA – American Heart Association. BP – blood pressure. CHC – community health center. HRSN – health-related social need.

Fig. 1 Modified CONSORT Diagram for Cluster Randomized Trial. *Legend.* AHA – American Heart Association. BP – blood pressure. CHC – community health center. HRSN – health-related social need

resources, community-informed patient education materials, and FBO-community-CHC linkage tools.

Practice-Level Facilitation Activities. The practice facilitator will work with the PF clinics for 24 months to support the implementation of the adapted Kaiser bundle workflows. Immediately prior to the start of the facilitated implementation phase (months 1–3 of the UH3 Phase), the practice facilitator will perform an initial assessment and develop an action plan for implementation that reflects practice readiness and needs. They will meet with practices approximately once per

month. The practice facilitator will not perform primary data collection but will assist practices in using their EHRs to develop reports to support performance monitoring and facilitate modification to the EHR to support clinical decision support and effective documentation for the adapted Kaiser bundle.

Education and training

We will provide training materials and resources to promote reliable and accurate use of automated BP cuffs, which the study provided to the FBOs and CHCs for use in this study. As with the current RMA training program, we will establish competency-based criteria to "certify" RMAs and study coordinators to accurately measure BP using these automated cuffs.

Capacity building

The study team and Steering Committee identified the following capacity building and engagement activities for CHCs and FBOs: 1) co-learning; 2) raising awareness of the partnership; 3) collaborative interpretation of results and manuscript preparation; and 4) partnership involvement in implementation [60].

BP Champions

We will engage BP champions in the CHCs to work closely with the practice facilitator and serve as the main point of contact with the study team. The champion will also be trained on the quarterly hypertension reports and will lead review with the practice manager and primary care clinicians. Our CHC partners have established processes for selecting champions for similar practice change initiatives that we will follow in this study, which can include champions shared across practice sites within their respective networks.

Measures

Assessment of context

We will assess barriers and facilitators within each service system (FBOs and CHCs) from the perspective of

Table 3 Implementation outcomes

	Variable/Construct	Measure(s)/Metrics	Source	Method
RE-AIM Implementation Evaluation Framework	Reach	1. Proportion of enrolled community members (study participants) engaged in the intervention 2. Proportion of eligible patients in community who express interest in the Kaiser bundle	EHR/Ad EHR/Ad	— —
	Effectiveness (of the clinical intervention)	Effect size of Kaiser bundle (BP control rate)	BP measurement	
	Adoption	Number and proportion of delivery agents that deliver assigned component(s) of the Kaiser bundle to study participants (specific to FBO and CHC contexts)	EHR	—
	Implementation			
	a. Acceptability	Acceptability of Intervention Measure (AIM) [50] 4-items (α = .85)	L, Im, PF	S
	b. Appropriateness	Intervention Appropriateness Measure (IAM) [50] 4-items (α = .91)	L, Im, PF	S
	c. Cost	Cost capture survey [61] time-driven activity-based costing methods [62] BP control services provided	Im, PF, R EHR	S —
	d. Feasibility	Feasibility of Intervention Measure (FIM) [50] 4-items (α = .89)	L, Im, PF	S
	e. Fidelity	FACITS system [63] to assess fidelity to the PF protocol (PF arm only)	Im, PF, Ad	S
	Sustainment	CHCs: Clinical Sustainability Assessment Tool (CSAT)Short Form [64], 7 domains, 21 items total FBOs: Program Sustainability Assessment Tool (PSAT) Short Form [64], 8 domains, 40 items total Sustainment of Kaiser bundle activities, use of program tools, etc	L L EHR	S, I S, I —

Legend. Sources: *Ad* Administrative data from the Eureka platform, *Im* implementers (CHC & FBO staff), *PF* Practice Facilitators, *L* leaders, *P* patients, *R* research team. Methods: *Ad* Administrative or publicly available surveillance data, *I* implementation team and CHC staff focus groups, *S* survey

Other Abbreviations. *BP* blood pressure, *CHC* community health center, *EHR* electronic health record, *FACITS* Facilitation Activity & Intervention Tracking System, *FBO* faith-based organization

workers in these settings using brief surveys and focus groups with FBO RMAs and CHC clinicians/leadership/staff.

Implementation outcomes

Table 3 contains the implementation outcomes, operationalized according to the RE-AIM evaluation framework [46]. The sources and method of data collection are also noted.

BP outcomes

The main clinical effectiveness measurement are the BP readings of participants in the community-based hypertension registry at study entry and 12 months post-enrollment. Trained study staff (coordinators and RMAs) will measure BP using study-provided BP cuffs to ensure appropriate calibration and reduce variability in method.

Participant outcomes

Participants enrolled in Eureka will complete surveys at baseline, 4-months, 8-months, and 12-months post-enrollment about factors related to BP control, which include health behaviors (e.g., diet, physical activity), adherence, and HRSNs.

Strategy tracking

Fidelity to individual strategies as well as to the study's implementation protocol will be captured using two methods. For PF, the independent variable, we will use the Facilitation Activity & Intervention Tracking System [63], developed in prior studies by members of the team, to continuously monitor activities for any unusual patterns or changes. Overall, the Longitudinal Implementation Strategy Tracking System (LISTS) [65, 66], designed to be used in conjunction with the IRLM, uses a timeline follow-back procedure, reported monthly, for implementation researchers to track changes in strategies, focused on: adding a new strategy, changing an existing strategy (e.g., actor, dose), and discontinuing a strategy. Use of LISTS began during the UG3 phase and will continue throughout the project period.

Statistical analysis plan and power

Implementation outcome: Reach

The primary analysis is to compare the reach of a adapted Kaiser bundle in CHCs randomized to implementation with vs. without PF over a two-year period of implementation support. Reach is defined as receipt of one or more clinical components of the Kaiser bundle (e.g., single pill combination therapy, BP checks per protocol) and is yes [1]/no[0] per participant enrolled in Eureka. The reach metric is equally applicable across the two arms. A multilevel logistic regression will be used to account for the clustered design. Reach at post-intervention will be modelled as a function of intervention while adjusting for covariates known to be risk factors for BP control: pre-intervention BP control status, systolic BP, age, sex, race, body mass index, physical activity, smoking and alcohol drinking status, highest educational status, health insurance coverage, history of diabetes, chronic kidney disease, patient recruitment source (FBO or CHC) (all prior are patient-level), provider specialty (clinician-level), and neighborhood deprivation index (clinic-level). PF will be conducted by only one practice facilitator; thus, we do not expect to use heterogeneous variance structures. Primary analyses will be based on intention-to-treat approach (including all participants in the Eureka platform, i.e., those consented to and eligible for the study). Degrees of freedom will be calculated using the Kenward-Roger method. Parameters needed for power calculation in our study—particularly intraclass correlation (ICC), coefficient of variation (CV), and proportion of variation in the outcome explained—were estimated using data from the EHRs of the participating clinics. We found an ICC of 0.017, CV of 0.35, and variation explained of 6.9% from a mixed-effect logistic regression model using data from 10 South Side CHC clinics. To ensure sufficient power, we doubled the ICC to 0.034 in our power calculation. The outcome was controlled BP for the $_i$th individual in the $_j$th clinic. Adjusted baseline covariates include baseline BP control, systolic and diastolic BP, age, sex, race, smoking, history of diabetes, chronic kidney disease, and clinic size.

Using the NIH sample size calculator for a two-arm parallel cluster-randomized trial, we will need a total of 16 clusters (8 per arm) to detect an effect size (increase in the proportion of eligible individuals who received Kaiser intervention component) of at least 17% while using an analysis of a simple difference, a cluster size of 300 patients with hypertension, a power of 90%, an alpha of 0.05, control arm reach rate of 60%, and our calculated ICC of 0.034, cluster size CV of 0.35, and 6.9% proportion of variation in the outcome explained by adjusted covariates. Allowing for 20% drop-out, a sample of 360 participants is needed from each clinic, resulting in a total sample size of 5,760 with approximately half ($n=2{,}880$) participants in each arm. In our preliminary study using data from 10 South Side clinics, we identified on average 1,500 eligible patients with hypertension per clinic per year. Although there is not a large body of literature on which to base our expected effect size, in one rigorous study conducted in Veterans Health Administration primary care sites, reach increased from 46.4% to 65.4% (19%) after the introduction of PF [67].

Secondary implementation outcomes are specified in Table 3 and include adoption of bundle components by

clinicians and RMAs; acceptability, appropriateness, and feasibility of each component of the adapted Kaiser bundle; fidelity of strategy and intervention delivery (described above); implementation costs (described in Implementation Costing, below); and sustainability of the intervention and implementation strategies specific to context.

Effectiveness Outcome: BP control

The main health-related effectiveness aim is to compare the proportion of patients with controlled hypertension in the intervention and control arms at one year (12 months) after each participant's enrollment (i.e., the consent date in Eureka). These metrics apply equally across both arms. We will examine differences in BP control by implementation strategy condition (with PF vs. without PF). The primary health outcome is BP control (yes [1]/no[0]) defined as an average systolic BP ≤ 140 mmHg or an average diastolic BP ≤ 90 mmHg. A multilevel logistic regression will be used to account for the clustered design in a cohort sample with a BP measurement at two timepoints (baseline and 12-months). Post-intervention BP control will be modeled as a function of intervention, adjusting for pre-intervention BP control status and other covariates. The same patient-, clinician-, and clinic-level covariates as above will be included. Primary analyses will be based on intention-to-treat.

Concerning power, in a study that adapted the Kaiser bundle for safety-net clinics, the control rate was 66% after two years in AA/B adults [68]. Assuming a power of 90%, alpha of 0.05, ICC of 0.034, control arm proportion of BP control of 66%, and 6.9% proportion of variation in the outcome explained due patient and physician level covariates, we will need at 16 total clusters (8 clusters per arm) to see an effect size of at least 16% using an analysis of a simple difference. Allowing for 20% drop-out, a sample of 360 participants is needed from each clinic ($n = 2880$ per arm).

Qualitative and mixed-methods analysis

A trained team of investigators and RMAs will use Rapid Qualitative Analysis [69] to (a) conduct content analysis and identify themes then (b) develop 'summary templates [70] from the focus group transcripts. For reliability, a random selection of 20% of recorded time will be double-coded [71]. Disagreements in coding will be resolved via expert consensus. Mixed-methods analysis will include "merge the data" [72], which involves bringing together quantitative and qualitative data through complementarity [73, 74].

Implementation costing

Cost analysis is central to the implementation evaluation and for providing data of use to potential adopters of the adapted Kaiser bundle (e.g., administrators, policy makers) implemented in the manner proposed. We will: (a) estimate the cost associated with implementing the adapted Kaiser bundle, and (b) assess the short-term cost-effectiveness of the intervention relative to BP control as usual. Both analyses will be conducted from the perspective of an adopting community and separated into costs borne by FBOs and CHCs. Time-driven activity-based costing methods [62] will be employed to estimate costs associated with adapting the Kaiser bundle, training providers and other involved individuals, implementer delivery time, PF activities, and other personnel time to support implementation. Discrete implementation strategy costs will be aggregated to estimate total implementation costs, and costs will be estimated for each phase of EPIS, as in prior implementation studies [75, 76]. An activity-based costing approach will allow us to value activities both locally (Chicago) and from national data sources (e.g., Current Population Survey, US Department of Labor), providing estimates relevant for scale-up in other communities nationwide. A cost-effectiveness analysis (CEA) will be undertaken to assess economic benefit. Consistent with most CEAs, we hypothesize that the additional costs associated with the adapted Kaiser bundle will lead to an increase in the BP control rate, compared to the change in BP control rate in a control community during the same period. The trade-off between cost and effectiveness will be calculated via an incremental cost-effectiveness ratio (ICER), where $ICER = (cost_{Kaiser} - cost_{controls}) / (effectiveness_{Kaiser} - effectiveness_{controls})$, $cost_{Kaiser} - cost_{controls}$ is the implementation cost of the community-adapted Kaiser bundle (i.e., the costs above and beyond usual BP control in the comparison community), and $effectiveness_{Kaiser} - effectiveness_{controls}$ is the percentage improvement in BP control rate in the intervention community minus the percentage improvement in the comparison community during the same time period. We will estimate the precision of the CEAs using a bootstrapping approach [77]. A series of 1,000 random samples will be drawn with replacement from the data. Thus, to replicate our estimates of the costs and effectiveness, we will randomly sample both groups 1,000 times and recompute cost and effectiveness after each resampling. Using this bootstrapping technique, we will develop cost-effectiveness acceptability curves [77] that give the probability that the CEA falls below thresholds that clinicians and policymakers deem to be relevant for decision making (e.g., $ per 1% improvement in BP control rate).

Discussion

Alarming cardiovascular health disparities persist between AA/B and non-Hispanic White individuals in the United States [78, 79]. The CIRCL-Chicago study is poised to provide evidence of health clinic- and community-level implementation strategies to improve BP control among patients and community members in Chicago's South Side community that could translation to similar urban areas nationally and elsewhere.

The CIRCL-Chicago study protocol underwent several major changes from submission of the grant application in 2019 to what is presented in this paper. As described in Smith et al. [42], these changes were by design. The first (UG3) phase of the biphasic award brought together diverse community members and implementation partners to refine the protocol with an explicit goal of interventions, strategies, and study designs that were acceptable to the community, higher likelihood of sustainability, and scientifically rigorous [11]. Through consultation with the funder, we changed from a quasi-experimental design to a rigorous test of a single evidence-based implementation strategy (PF) at the CHC level using a parallel cluster-randomized trial design.

The change in study design required active enrollment and consenting of participants, which led to our adoption of the Eureka platform for the hypertension registry and electronic data capture, a critical component of the Kaiser bundle. This change represents one of the most challenging aspects of the study—participant recruitment and enrollment. The total number of participants to be recruited for the study based on power calculations ($N=5{,}760$) is a small portion of those eligible in the CHCs (approximately 24,000) and broader South Side community but is nonetheless a large number for the time frame and resources available (e.g., staff time, inability to provide participant incentives).

Finally, in addition to a rigorous test of PF on increasing the reach of the adapted Kaiser bundle in CHCs, by applying the Dynamic Adaptation Process model [44], we will develop and evaluate a community-driven adaptation for a community experiencing cardiovascular health disparities. Ensuring the fit of an intervention developed in a different context with the resources of the local context and the priorities and preferences of the community has the potential for great impact on health disparities.

Abbreviations

AA/B	African American and Black
BP	Blood pressure
CEA	Cost-effectiveness analysis
CHC	Community health center
CIRCL-Chicago	Community Intervention to Reduce CardiovascuLar Disease in Chicago
CV	Coefficient of variation
DASH	Dietary Approaches to Stop Hypertension
DECIPHeR	Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Risk
HER	Electronic health record
FBO	Faith-based organization
HRSN	Health-related social needs
HRSR	Health-related social risks
ICC	Intraclass correlation
ICER	Incremental cost-effectiveness ratio
IRB	Institutional Review Board
IRLM	Implementation Research Logic Model
LISTS	Longitudinal Implementation Strategy Tracking System
NIH	National Institutes of Health
Pastors4PCOR	Pastors for Patient-Centered Outcomes Research
PF	Practice facilitation
REDCap	Research Electronic Data Capture
RMA	Research Ministry Ambassador
TRCDO	Total Resource Community Development Organization

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Authors' contributions

JDS conceived of the study with ANK, PD, DL, STL, MCM, RK, NK, and TLW. JDS drafted the final version of the paper. AJC, OAS, JLM, JH, JB, EMA, FSA, EAP, LLR, RD, TG, NK, QY, and RW contributed to the development of study procedures and data collection processes across the community health centers and faith-based organizations. YGT led the design of the statistical analysis plan and conducted the power analysis. JB and TLW specifically contributed to the protocol for practice facilitation. PD contributed specifically to the role of the Research Ministry Ambassadors and Pastors for Patient-Centered Outcomes Research in this study. All authors contributed to refining and finalizing the protocol. All authors read and approved the final manuscript.

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Data availability

Additional details in the form of a full study protocol are available by request to the corresponding author.

Declarations

Ethics approval and consent to participate

This study was approved by the University of Utah Institutional Review Board on 03–26-2024 (Protocol ID: IRB_00174767). Participant consent will be collected via the Eureka platform at time of study enrollment. Survey respondents (e.g., health system employees, research ministry ambassadors)

will complete e-consent via REDCap at each administration. Consent from the community health centers and faith-based organizations was not required for their participation.

Consent for publication
Not applicable.

Competing interests
J.D. Smith is an Associate Editor of *Implementatiosn Science.* A.N. Kho discloses that he was founder and co-owner of HealthDataLink LLC, a company acquired in 2019 by Datavant, where he is currently an advisor and stockholder. S.T. Lindau discloses that she is founder and co-owner of NowPow LLC, a company acquired in 2021 by Unite Us LLC, where she is currently an advisor and stockholder. She is president of MAPSCorps, a 501c3 nonprofit organization, and serves on other nonprofit boards. Neither the University of Chicago nor the University of Chicago Medicine endorses or promotes any NowPow, Unite Us or MAPSCorps product or service. S.T. Lindau holds debt in Glenbervie Health LLC and owns health care–related investments managed by third parties. S.T. Lindau is a contributor to UpToDate, Inc. The University of Chicago receives royalties from UpToDate, Inc. T.L. Walunas receives research funding from Gilead Sciences for work related to COVID in immunosuppressed populations. Q. R. Youmans has served on an advisory board for American Regent.

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References

1. Muntner P, Hardy ST, Fine LJ, Jaeger BC, Wozniak G, Levitan EB, Colantonio LD. Trends in Blood Pressure Control Among US Adults With Hypertension, 1999–2000 to 2017–2018. JAMA. 2020;324:1190–200.
2. Mozaffarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, Cushman M, Das SR, de Ferranti S, Després J-P, Fullerton HJ, et al. Heart Disease and Stroke Statistics-2016 Update: A Report From the American Heart Association. Circulation. 2016;133:e38-360.
3. Kochanek KD, Arias E, Anderson RN: How did cause of death contribute to racial differences in life expectancy in the United States in 2010? . Washington, DC: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics; 2013.
4. Mensah GA, Mokdad AH, Ford ES, Greenlund KJ, Croft JB. State of Disparities in Cardiovascular Health in the United States. Circulation. 2005;111:1233–41.
5. Lackland DT. Racial differences in hypertension: implications for high blood pressure management. Am J Med Sci. 2014;348:135–8.
6. Manze M, Rose AJ, Orner MB, Berlowitz DR, Kressin NR. Understanding racial disparities in treatment intensification for hypertension management. J Gen Intern Med. 2010;25:819–25.
7. Kyanko K, Franklin R. AS: Adherence to chronic disease medications among New York City Medicaid participants. J Urban Health. 2013;90:323–8.
8. Adinkrah E, Bazargan M, Wisseh C, Assari S. Adherence to Hypertension Medications and Lifestyle Recommendations among Underserved African American Middle-Aged and Older Adults. Int J Environ Res Public Health. 2020;17:6538.
9. Armstrong K, Ravenell KL, McMurphy S, Putt M. Racial/ethnic differences in physician distrust in the United States. Am J Public Health. 2007;97:1283–9.
10. Flynn SJ, Ameling JM, Hill-Briggs F, Wolff JL, Bone LR, Levine DM, Roter DL, Lewis-Boyer L, Fisher AR, Purnell L, et al. Facilitators and barriers to hypertension self-management in urban African Americans: perspectives of patients and family members. Patient Prefer Adherence. 2013;7:741–9.
11. Philbin S, Johnson RE, Pedamallu H, Carroll AJ, Ekong A, et al. Planning the Implementation of a Multilevel Blood Pressure Control Intervention in Chicago: Community and Clinical Perspectives. Ethn Dis. 2023;DECIPHeR(Special Issue): 60–7.
12. Smith JD, Davis P, Kho AN: Community-Driven Health Solutions on Chicago's South Side. Stanford Soc Innov Rev. 2021;19(3):A27–9.
13. Jaffe MG, Lee GA, Young JD, Sidney S, Go AS. Improved Blood Pressure Control Associated With a Large-Scale Hypertension Program. JAMA. 2013;310:699–705.
14. Wong W, Jaffe M, Wong M, Dudl RJ. Community Implementation and Translation of Kaiser Permanente's Cardiovascular Disease Risk-Reduction Strategy. The Permanente journal. 2011;15:36–41.
15. Schulz A, Northridge ME. Social determinants of health: Implications for environmental health promotion. Health Educ Behav. 2004;31:455–71.
16. Pampel FC, Krueger PM, Denney JT. Socioeconomic disparities in health behaviors. Ann Rev Sociol. 2010;36:349–70.
17. Graham G. Population-based approaches to understanding disparities in cardiovascular disease risk in the United States. International Journal of General Medicine. 2014;7:393–400.
18. Thomas SB, Quinn SC, Billingsley A, Caldwell C. The characteristics of northern black churches with community health outreach programs. Am J Public Health. 1994;84:575–9.
19. Chaves M, Tsitsos W. Congregations and Social Services: What They Do, How They Do It, and with Whom. Nonprofit Volunt Sect Q. 2001;30:660–83.
20. Chatters LM, Taylor RJ, Bullard KM, Jackson JS. Race and ethnic differences in religious involvement: African Americans, Caribbean blacks and non-Hispanic whites. Ethn Racial Stud. 2009;32:1143–63.
21. Fitchett G, Murphy PE, Kravitz HM, Everson-Rose SA, Krause NM, Powell LH. Racial/Ethnic Differences in Religious Involvement in a Multi-Ethnic Cohort of Midlife Women. J Sci Study Relig. 2007;46:119–32.
22. Religious Beliefs and Practices. Pew Research Center, Washington DC 2009.
23. Tussing-Humphreys LM, Thomson JL, Onufrak SJ. A Church-Based Pilot Study Designed to Improve Dietary Quality for Rural, Lower Mississippi Delta, African American Adults. J Relig Health. 2015;54:455–69.
24. Campbell MK, Demark-Wahnefried W, Symons M, Kalsbeek WD, Dodds J, Cowan A, Jackson B, Motsinger B, Hoben K, Lashley J, et al. Fruit and vegetable consumption and prevention of cancer: the Black Churches United for Better Health project. Am J Public Health. 1999;89:1390–6.
25. Oexmann MJ, Ascanio R, Egan BM. Efficacy of a church-based intervention on cardiovascular risk reduction. Ethn Dis. 2001;11:817–22.
26. Schoenthaler AM, Lancaster KJ, Chaplin W, Butler M, Forsyth J, Ogedegbe G. Cluster Randomized Clinical Trial of FAITH (Faith-Based Approaches in the Treatment of Hypertension) in Blacks. Circulation Cardiovascular Quality and Outcomes. 2018;11:e004691.
27. Mills KT, Laurent J, Allouch F, Payne MJ, Gustat J, He H, Alvarado F, Anderson A, Bundy JD, Chen J, et al: Engaging Predominantly Black Churches in an Intervention to Improve Cardiovascular Health and Reduce Racial Inequities. Ethnicity and Disease. 2024;DECIPHeR:89–95.
28. Canoy D, Nazarzadeh M, Copland E, Bidel Z, Rao S, Li Y, Rahimi K. How Much Lowering of Blood Pressure Is Required to Prevent Cardiovascular Disease in Patients With and Without Previous Cardiovascular Disease? Curr Cardiol Rep. 2022;24:851–60.
29. Victor RG, Lynch K, Li N, Blyler C, Muhammad E, Handler J, Brettler J, Rashid M, Hsu B, Foxx-Drew D, et al. A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops. N Engl J Med. 2018;378:1291–301.
30. Chinman M, Woodward EN, Curran GM, Hausmann LRM. Harnessing Implementation Science to Increase the Impact of Health Equity Research. Med Care. 2017;55:S16–23.
31. Perrino T, Beardslee W, Bernal G, Brincks A, Cruden G, Howe G, Murry V, Pantin H, Prado G, Sandler I. Toward scientific equity for the prevention of depression and depressive symptoms in vulnerable youth. Prev Sci.2015;16:642–65.
32. Bonevski B, Randell M, Paul C, Chapman K, Twyman L, Bryant J, Brozek I, Hughes C. Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. BMC Med Res Methodol. 2014;14:42.
33. Huang K-Y, Kwon SC, Cheng S, Kamboukos D, Shelley D, Brotman LM, Kaplan SA, Olugbenga O, Hoagwood K. Unpacking Partnership,

Engagement, and Collaboration Research to Inform Implementation Strategies Development: Theoretical Frameworks and Emerging Methodologies. Frontiers in Public Health. 2018;6:190.
34. Boothroyd RI, Flint AY, Lapiz AM, Lyons S, Jarboe KL, Aldridge WA II. Active involved community partnerships: co-creating implementation infrastructure for getting to and sustaining social impact. Translational Behavioral Medicine. 2017;7:467–77.
35. Holt CL, Chambers DA. Opportunities and challenges in conducting community-engaged dissemination/implementation research. Translational Behavioral Medicine. 2017;7:389–92.
36. Goodman MS, Sanders Thompson VL. The science of stakeholder engagement in research: classification, implementation, and evaluation. Translational Behavioral Medicine. 2017;7:486–91.
37. Mensah George A, Cooper Richard S, Siega-Riz Anna M, Cooper Lisa A, Smith Justin D, Brown CH, Westfall John M, Ofili Elizabeth O, Price LeShawndra N, Arteaga S, et al. Reducing Cardiovascular Disparities Through Community-Engaged Implementation Research. Circ Res. 2018;122:213–30.
38. Kho A, Daumit GL, Truesdale KP, Brown A, Kilbourne AM, Ladapo J, Wali S, Cicutto L, Matthews AK, Smith JD, et al. The National Heart Lung and Blood Institute Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Alliance. Health Serv Res. 2022;57(Suppl. 1):20-31.
39. Johnson R, Ingram D, Gordon BS, Davis P, Greer-Smith R. Community-Initiated Research Engagement: Equitable Partnership Delivering Research-Ready Faith-Based Ambassadors. Progress in Community Health Partnerships: Research, Education, and Action. 2020;14:197–206.
40. Taylor EF, Machta RM, Meyers DS, Genevro J, Peikes DN. Enhancing the Primary Care Team to Provide Redesigned Care: The Roles of Practice Facilitators and Care Managers. The Annals of Family Medicine. 2013;11:80.
41. Wang A, Pollack T, Kadziel LA, Ross SM, McHugh M, Jordan N, Kho AN. Impact of Practice Facilitation in Primary Care on Chronic Disease Care Processes and Outcomes: a Systematic Review. J Gen Intern Med. 2018;33:1968–77.
42. Smith JD, Carroll AJ, Sanuade OA, Johnson R, Abramsohn EM, Abbas H, Ahmad FS, Eggleston A, Lazar D, Lindau ST, et al. Process of Engaging Community and Scientific Partners in the Development of the CIRCLChicago Study Protocol. Ethn Dis. 2024;DECIPHeR:18–26.
43. Moullin JC, Dickson KS, Stadnick NA, Rabin B, Aarons GA. Systematic review of the Exploration, Preparation, Implementation, Sustainment (EPIS) framework. Implement Sci. 2019;14:1.
44. Aarons GA, Green AE, Palinkas LA, Self-Brown S, Whitaker DJ, Lutzker JR, Silovsky JF, Hecht DB, Chaffin MJ. Dynamic adaptation process to implement an evidence-based child maltreatment intervention. Implement Sci. 2012;7:32.
45. Perez L, Dopp A, Ayele R, Reardon C, Smith JD, Heubschmann A: Development of an integrated implementation determinant framework for shared learning in an alliance of community-engaged health equity implementation research. In 15th Annual Conference on the Science of Dissemination and Implementation in Health; Washington, DC. 2022
46. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, Ory MG, Estabrooks PA. RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review. Front Public Health. 2019;7:64.
47. Smith JD, Li DH, Rafferty MR. The Implementation Research Logic Model: a method for planning, executing, reporting, and synthesizing implementation projects. Implement Sci. 2020;15:84.
48. Hypertension: Adults Diagnosed with High Blood Pressure [https://www.chicagohealthatlas.org/indicators/hypertension]
49. Carey RM, Whelton PK. Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Synopsis of the 2017 American College of Cardiology/American Heart Association Hypertension Guideline. Ann Intern Med. 2018;168:351–8.
50. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, Boynton MH, Halko H. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci. 2017;12:108.
51. Solberg LI, Asche SE, Margolis KL, Whitebird RR. Measuring an Organization's Ability to Manage Change: The Change Process Capability Questionnaire and Its Use for Improving Depression Care. Am J Med Qual. 2008;23:193–200.
52. Smith JD, Rafferty MR, Heinemann AW, Meachum MK, Villamar J, Lieber RL, Brown CH. Pragmatic adaptation of implementation research measures for a novel context and multiple professional roles: a factor analysis study. BMC Health Serv Res. 2020;20:257.
53. Armenakis AA, Bernerth JB, Pitts JP, Walker HJ. Organizational Change Recipients' Beliefs Scale: Development of an Assessment Instrument. J Appl Behav Sci. 2007;43:481–505.
54. Aarons GA, Ehrhart MG, Farahnak LR. The implementation leadership scale (ILS): development of a brief measure of unit level implementation leadership. Implement Sci. 2014;9:45.
55. Curran GM, Landes SJ, McBain SA, Pyne JM, Smith JD, Fernandez ME, Chambers DA, Mittman BS. Reflections on 10 Years of Effectiveness-Implementation Hybrid Studies. Frontiers in Health Services—Implementation Science. 2022;2:1053496.
56. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ : British Medical Journal. 2012;345: e5661.
57. Justin D. Smith, Allison J. Carroll, Olutobi A. Sanuade, Rebecca Johnson, Emily M. Abramsohn, Hiba Abbas, Faraz S. Ahmad, Alice Eggleston, Danielle Lazar, Stacy Tessler Lindau, Megan McHugh, Nivedita Mohanty, Sarah Philbin, El A. Pinkerton, Linda L. Rosul, James L. Merle, Yacob G. Tedla, Theresa L. Walunas, Paris Davis, Abel Kho; Process of Engaging Community and Scientific Partners in the Development of the CIRCL-Chicago Study Protocol. Ethnicity and Disease 1 December 2023; DECIPHeR (Special Issue): 18–26.
58. Aarons GA, Green AE, Palinkas LA, Self-Brown S, Whitaker DJ, Lutzker JR, Silovsky JF, Hecht DB, Chaffin MJ. Dynamic adaptation process to implement an evidence-based child maltreatment intervention. Implement Sci. 2012;7:1–9.
59. Practice Facilitation [https://pcmh.ahrq.gov/page/practice-facilitation]
60. Cooper C, Watson K, Alvarado F, Carroll AJ, Carson SL, Donenberg G, Ferdinand KC, Islam N, Johnson R, Laurent J, et al: Community Engagement in Implementation Science: the Impact of Community Engagement Activities in the DECIPHeR Alliance. Ethnicity and Disease. 2024;DECIPHeR:52–59.
61. Ritzwoller DP, Sukhanova A, Gaglio B, Glasgow RE. Costing behavioral interventions: a practical guide to enhance translation. Ann Behav Med. 2009;37:218–27.
62. Kaplan RS, Witkowski M, Abbott M, Guzman AB, Higgins LD, Meara JG, Padden E, Shah AS, Waters P, Weidemeier M, et al. Using Time-Driven Activity-Based Costing to Identify Value Improvement Opportunities in Healthcare. J Healthc Manag. 2014;59:399–412.
63. Walunas TL, Ye J, Bannon J, Wang A, Kho AN, Smith JD, Soulakis N. Does coaching matter? Examining the impact of specific practice facilitation strategies on implementation of quality improvement interventions in the Healthy Hearts in the Heartland study. Implement Sci. 2021;16:33.
64. Malone S, Prewitt K, McKay V, Zabotka L, Bacon C, Luke DA. Lowering the burden: Shorter versions of the Program Sustainability Assessment Tool (PSAT) and Clinical Sustainability Assessment Tool (CSAT). Implementation Science Communications. 2024;5:113.
65. Smith JD, Merle J, Webster KA, Cahue S, Penedo FJ, Garcia SF. Tracking dynamic changes in implementation strategies over time within a hybrid type 2 trial of an electronic patient-reported oncology symptom and needs monitoring program. Frontiers in Health Services. 2022;2: 983217.
66. Smith JD, Norton WE, Mitchell SA, Cronin C, Hassett MJ, Ridgeway JL, Garcia SF, Osarogiagbon RU, Dizon DS, Austin JD, et al. The Longitudinal Implementation Strategy Tracking System (LISTS): feasibility, usability, and pilot testing of a novel method. Implementation Science Communications. 2023;4:153.
67. Chang ET, Oberman RS, Cohen AN, et al. Increasing Access to Medications for Opioid Use Disorder and Complementary and Integrative Health Services in Primary Care. J Gen Intern Med. 2020;35(Suppl 3):918–26.
68. Fontil V, Gupta R, Moise N, Chen E, Guzman D, McCulloch CE, Bibbins-Domingo K. Adapting and Evaluating a Health System Intervention From Kaiser Permanente to Improve Hypertension Management and Control in a Large Network of Safety-Net Clinics. Circ Cardiovasc Qual Outcomes. 2018;11: e004386.
69. Gale RC, Wu J, Erhardt T, Bounthavong M, Reardon CM, Damschroder LJ, Midboe AM. Comparison of rapid vs in-depth qualitative analytic methods from a process evaluation of academic detailing in the Veterans Health Administration. Implement Sci. 2019;14:11.

70. Hamilton AB: Qualitative Methods in Rapid Turn-Around Health Services Research. In VA Women's Health Research Network; 2013.
71. Cicchetti DV, Sparrow SS. Developing criteria for establishing the interrater reliability of specific items in an inventory. Am J Ment Defic. 1981;86:127–37.
72. Palinkas LA, Rhoades Cooper B: Mixed methods evaluation in dissemination and implementation science. In Dissemination and implementation research in health. 2nd edition. Edited by Brownson RC, Colditz GA, Proctor EK. New York, NY: Oxford University Press; 2017
73. Palinkas LA, Aarons GA, Horwitz S, Chamberlain P, Hurlburt M, Landsverk J. Mixed method designs in implementation research. Administration and Policy in Mental Health and Mental Health Services Research. 2011;38:44–53.
74. Aarons GA, Fettes DL, Sommerfeld DH, Palinkas LA. Mixed methods for implementation research: Application to evidence-based practice implementation and staff turnover in community-based organizations providing child welfare services. Child Maltreat. 2012;17:67–79.
75. Harris A, Jordan N, Carroll AJ, Graham AK, Wilson C, Berkel C, Smith JD. Costs of Implementing a Family-Based Intervention to Prevent Pediatric Obesity in Primary Care: a Budget Impact Analysis. Implementation Science Communications. 2023;4(1):59.
76. Jordan N, Graham AK, Berkel C, Smith JD. Costs of Preparing to Implement a Family-Based Intervention to Prevent Pediatric Obesity in Primary Care: a Budget Impact Analysis. Prev Sci. 2019;20:655–64.
77. O'Brien BJ, Briggs AH. Analysis of uncertainty in health care cost-effectiveness studies: an introduction to statistical issues and methods. Stat Methods Med Res. 2002;11:455–68.
78. Allison MA, Armstrong DG, Goodney PP, Hamburg NM, Kirksey L, Lancaster KJ, Mena-Hurtado CI, Misra S, Treat-Jacobson DJ, White Solaru KT, et al. Health Disparities in Peripheral Artery Disease: A Scientific Statement From the American Heart Association. Circulation. 2023;148:286–96.
79. Lofton H, Ard JD, Hunt RR, Knight MG. Obesity among African American people in the United States: A review. Obesity. 2023;31:306–15.

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