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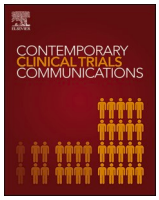

Evaluating chronic disease approaches to ameliorate tobacco-related health disparities: Study protocol of a hybrid type 1 implementation-effectiveness trial

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ABSTRACT

Background: Black, Indigenous, and People of Color (BIPOC) communities experience higher prevalence of cardiovascular disease and related chronic conditions compared to White communities due to disparities in tobacco exposure. Smoking can be effectively treated but evidence-based treatments are less likely to be offered to or used by BIPOC patients. We present the study protocol of the Smoking Cessation Outreach for Racial Equity (SCORE) trial that tests the effect of adding longitudinal care coordination to current standard of care for smoking cessation to promote health equity among BIPOC patients.

Methods: Longitudinal Proactive Outreach (LPO; 4 culturally tailored outreach call cycles over one year by motivational interviewing trained counselors to connect patients to cessation counseling and medication) will be added to the current standard of care, Ask-Advise-Connect (AAC; primary care providers asking all patients if they smoke, and if smoking, advising to quit and connecting to treatment). We will conduct a hybrid type 1 implementation-effectiveness trial to examine the direct effect of AAC + LPO (a multilevel health system intervention) vs. AAC on population-level combustible tobacco abstinence at 18 months and treatment utilization among 2000 BIPOC adults who smoke across two healthcare systems in Minnesota. Participants will be surveyed at 6, 12, and, 18 months post-enrollment to assess outcomes. The primary outcome is biochemically confirmed combustible cigarette abstinence at 18 months.

Discussion: LPO has potential to promote health equity by addressing barriers caused by structural racism, including access to care, care fragmentation, and provider racism, by systematically reaching out to all BIPOC patients who smoke.

Clinicaltrialsgov: NCT05671380.

1. Introduction

Black, Indigenous, and People of Color (BIPOC) communities in the US experience disproportionate health consequences from tobacco use, particularly those caused by commercial cigarette use. Cigarette smoking prevalence rates are higher among certain BIPOC groups compared to their White counterparts [1]. Among people who smoke, those who identify as BIPOC, compared to their White counterparts, experience greater morbidity and mortality from tobacco-related chronic diseases [2]. For example, Black Americans have significantly higher rates of hypertension than Whites and greater cardiovascular disease (CVD) mortality [3–7]. Although there are numerous evidence-based cessation treatments (EBCT) for tobacco cessation, BIPOC patients are less likely than White patients to be offered, receive, and utilize EBCT [8]. Structural racism, interpersonal racism, and discrimination affect access to and engagement with EBCTs and may contribute to their lower utilization among BIPOC patients [8,9]. Few interventions to promote use of EBCTs have been specifically developed, rigorously evaluated, or

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implemented for BIPOC patients [10,11].

Pharmacotherapy combined with behavioral counseling is the standard of care for smoking cessation [12]. The US Public Health Service recommends the use of the 5A's (Ask, Advise, Assess, Assist, and Arrange follow-up) in primary care encounters so that all patients who smoke have access to appropriate care [12]. These guidelines have been successful in identifying patients who smoke and increasing medication use during quit attempts. However, the combination of medication and counseling is used by only 5 % of patients during quit attempts with lower rates among BIPOC patients [8]. Existing healthcare system efforts fail to engage or retain BIPOC patients in cessation treatment programs [13]. Causal factors for this failure are complex and operate at multiple levels (e.g., patient, provider, healthcare system) [14].

Enhancing the capacity of physicians, clinics, and health systems to address tobacco use may be best addressed by system-level support. Two system-level models of care have been demonstrated to be effective for increasing treatment engagement. First, Ask-Advise-Connect (AAC) is a strategy where patients who accept referral are directly connected with Quitline cessation counseling, usually through a direct electronic referral in the electronic health record (EHR) or a portal web referral. AAC is a streamlined adaptation of the 5As with the goal of increasing behavioral counseling and minimizing the barriers to connection with a cessation treatment provider. AAC is increasingly being adopted as part of routine clinical care. Studies have found that AAC is effective for increasing engagement with Quitline [15,16], including among BIPOC communities, but data on long-term smoking abstinence is limited [17].

Second, proactive outreach is an evidence-based practice that leverages the power of the EHR for efficient and systematic identification of patients who smoke cigarettes. Patients are proactively engaged using telephone outreach to connect them to smoking cessation treatments [18]. In multiple RCTs, proactive outreach was effective in increasing the uptake of EBCTs including cessation pharmacotherapy and behavioral counseling as well as long-term smoking abstinence. In addition, proactive outreach programs are also judged to be highly cost effective with an incremental cost per quit ranging from $2766 to $4137 per quit [19,20]. Offering treatment to all patients outside of the medical encounter could reduce barriers among BIPOC patients created by negative experiences (e.g, discrimination) encountered with medical care [11].

Tobacco use is a chronic disease [12]. Both AAC and proactive outreach system-level interventions can be implemented as chronic care approaches. Healthcare systems may be reluctant to adopt proactive outreach as it may require more healthcare personnel resources than AAC. However, implementation of AAC alone is unlikely to effectively engage individuals with infrequent contact with the healthcare system or individuals whose providers have been less effective at addressing smoking. In a chronic care approach, Longitudinal Proactive Outreach (LPO) can also be used as an adjunct to AAC. LPO can improve the population reach of cessation interventions and promote health equity by engaging patients who are not actively seeking clinical care as well as those for whom care has not been offered by their physicians. Here, we present the study design and intervention protocols of the Smoking Cessation Outreach for Racial/ethnic Equity (SCORE) trial that uses a type 1 hybrid implementation-effectiveness design. In addition to assessing the effect of adding LPO to AAC, we will also assess ease of implementation of these interventions and health system staff perspectives of how LPO may be integrated (e.g., within the clinic or as part of a centralized hub program). This will help to address a critical problem in healthcare that is due to the slow rate at which research-supported treatments reach patients because of problems in dissemination and implementation [21–24].

This trial is a core project of the Center for Chronic Disease Reduction and Equity promotion Across Minnesota (C2DREAM), a regional collaboration involving the University of Minnesota, Hennepin Healthcare and Mayo Clinic and a part of the National Institute on Minority Health and Health Disparities (NIMHD) Health Equity Action Network (HEAN). C2DREAM aims to address racism at multiple levels as a central cause of disparities in cardiovascular disease and related chronic conditions among BIPOC communities in Minnesota. The proposed augmentation to AAC, LPO is a patient-targeted intervention uses an individualized (vs the one-size-fits-all AAC Model), person-centered motivational style with cultural tailoring to provide information to those with low health literacy. LPO, by using direct outreach and a patient-centered motivational approach, circumvents provider racism and structural determinants (e.g., provider access and time), and by being culturally tailored aims to improve expectations of treatment, reduce the perception of racism, and increase treatment use to increase smoking abstinence.

2. Methods

2.1. SCORE study design and overview

The study utilizes a Hybrid Type 1 implementation-effectiveness trial with randomization on the individual level. It will evaluate two chronic disease interventions to quantify the effectiveness of LPO when added to AAC among 2000 BIPOC adult patients who smoke at 27 primary care clinics in a safety-net, urban health system (Hennepin Healthcare) in Minneapolis, Minnesota (see Fig. 1) and 45 community-based outpatient clinics (95 % rural) within the Mayo Clinic Health System (MCHS) in Southeast and Southwest Minnesota. This study protocol has been approved by the University of Minnesota Institutional Review Board, which is serving as the single IRB. Clinical staff at all participating clinics will be trained to implement AAC using a package of implementation strategies consisting of didactic training and job aids. Registries of BIPOC patients who smoke will be created and used to invite individuals to participate in the study. Participants will be randomized to receive either AAC or AAC + LPO. The primary outcome will be biochemically-verified 7-day point-prevalence cigarette abstinence at 18 months. Because this study considers the population impact (at the health system level) of smoking cessation treatment, we will include all BIPOC patients who smoke, regardless of their interest in quitting at the time of enrollment. This contrasts with studies designed to test the efficacy of an intervention in participants who have indicated strong interest in quitting.

We will also assess readiness for implementation among participating clinics using the i-PARIHS framework which posits that success in implementation is defined as achievement of implementation goals, and results from the facilitation of implementing an innovation in

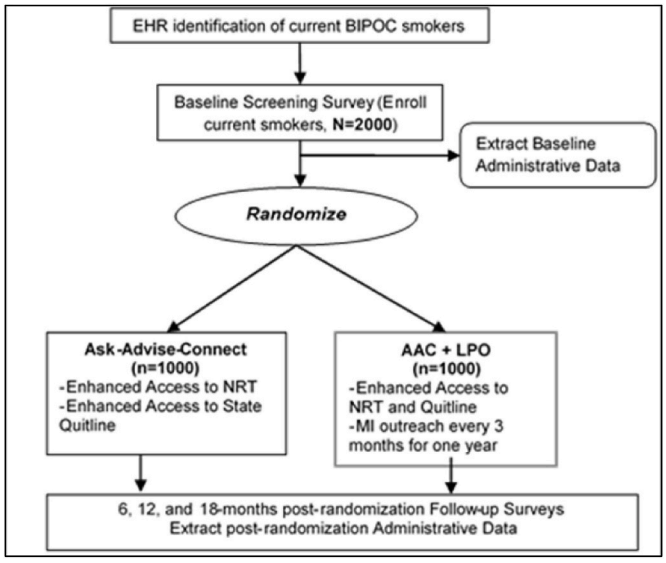

Fig. 1. Study overview.

collaboration with recipients in the local or regional health system. The core constructs in the i-PARIHS framework include facilitation, innovation, recipients, and context [25]. Facilitation refers to activities that aid in implementation. Innovation is a process of combining existing evidence and practice guidelines with clinical priorities and resources. Recipients include the individuals involved in implementation including BIPOC patients, clinical staff, and managers. Context involves the wider social, economic, and policy context that influences implementation, and information about the treatment setting.

2.2. Study aims

The SCORE trial has three primary aims: (1) Conduct a hybrid type 1 implementation-effectiveness RCT to examine the direct effect of AAC + LPO vs. AAC on population-level combustible cigarette abstinence at 18 months and treatment utilization among urban and rural BIPOC patients. We hypothesize that AAC + LPO will be associated with higher rates of combustible cigarette abstinence and combined pharmacotherapy and counseling than AAC at 18 months; (2) Examine the moderating effects of structural racism and daily interpersonal discrimination on intervention effectiveness. We hypothesize that the AAC + LPO intervention will be more effective for increasing rates of smoking abstinence and cessation treatment utilization for patients experiencing higher (versus lower) levels of structural racism and interpersonal discrimination; (3) Use a mixed methods approach to evaluate implementation outcomes of appropriateness, acceptability, and feasibility of AAC and LPO for BIPOC patients. We expect the implementation evaluation will identify factors that may impede or facilitate future implementation of these interventions among urban and rural health systems serving patients who smoke from BIPOC communities.

In an exploratory aim, we will use causal mediation analyses to explore the mechanisms responsible for the intervention effects. Specifically, we will test the hypothesis that the positive effects of the intervention will be stronger for patients with higher (vs lower) experiences with discrimination in healthcare settings, and that these effects will be mediated by greater increases in perceived behavioral control and intentions to quit/remain quit among patients in AAC + LPO vs AAC.

2.3. Theoretical framework

Because choosing to utilize treatment and ultimately to quit is affected by both social and cognitive factors, our theoretical framework (Fig. 2) utilizes constructs from Clark's Biopsychosocial Model of Racism and Social Cognitive Theory (SCT). SCT posits that health behavior is a function of self-efficacy, outcomes expectations, and structural barriers and facilitators [26]. SCT allows for explicit consideration of the way sociostructural factors operate through psychological mechanisms to produce behavioral effects [27]. The Biopsychosocial Model of Perceived Racism posits that health outcomes are a function environmental stimuli, the perception of environmental stimuli as racist or stressful, coping responses to stressful/racist stimuli and subsequent physiological and psychological stress responses [9]. Combined, these constructs create a framework to understand and evaluate the individual and environmental factors associated with the choice to utilize treatment, and ultimately, to quit smoking among BIPOC patients. Our framework emphasizes the role of experiences inside and outside the healthcare system and cognition and beliefs to accessing and using smoking cessation care. Our framework (left to right) begins with a presentation of the two interventions, "LPO + AAC" vs. "AAC" and uses the four round boxes to show how an individual could advance from an offer of care all the way to smoking abstinence. Beneath each step along the continuum to abstinence are the factors and experiences at the individual and environmental levels which can either promote or impede (as barriers) the journey to smoking abstinence.

Consistent with National Institute on Minority Health and Health Disparities (NIMHD) research framework, both interventions work at Community Level of influence (Safety Net Services) [28]. The interventions differ in that AAC relies on Interpersonal Level factors such as the patient-clinician relationship and medical decision making. Interpersonal factors are susceptible to perceived or real racism on the part of the patient and provider as well as competing demands for time that could affect the offer and acceptance of treatment. LPO, by contrast, works on the Individual Level, using an individualized (vs the one-size-fits-all AAC Model), person-centered motivational style with

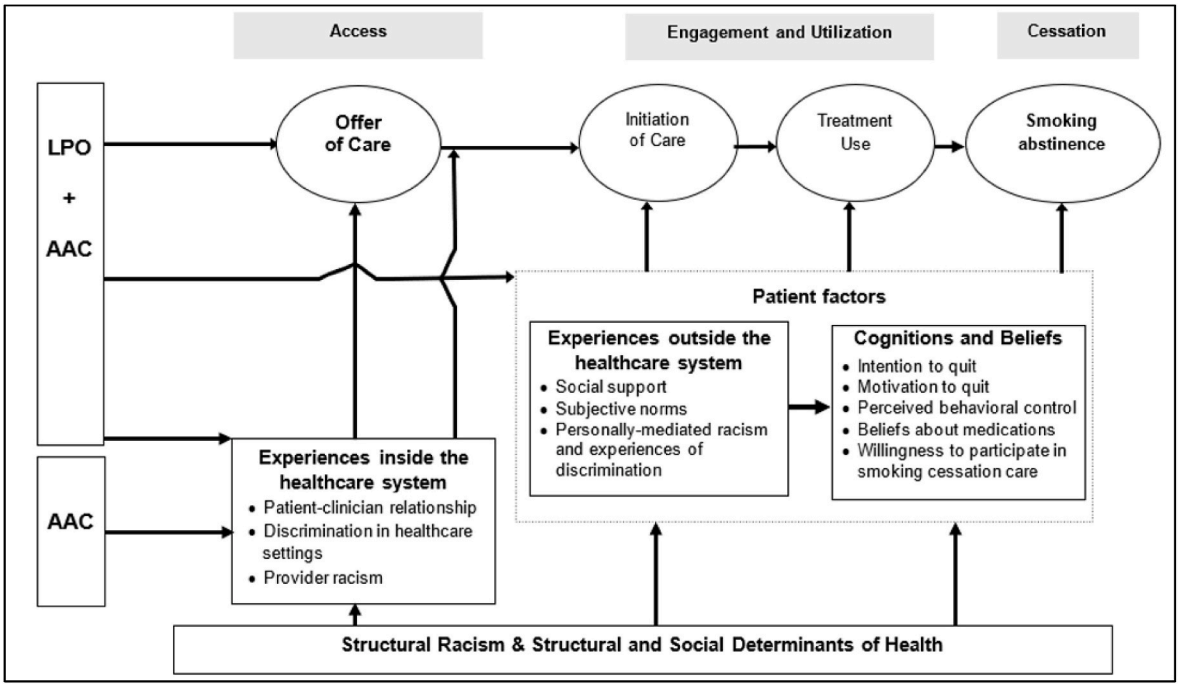

Fig. 2. Theoretical framework.

cultural tailoring to provide information to those with low health literacy. AAC alleviates structural determinants by facilitating a connection to smoking cessation treatment (e.g., connecting patients to the Quitline). The systematic referral of every patient who smokes to the Quitline or local health system cessation services could reduce bias in referrals which could be affected by provider racism. LPO, by using direct outreach and a patient-centered motivational approach, circumvents provider racism and structural determinants (e.g., provider access and time), and by being culturally tailored aims to improve expectations of treatment, reduce the perception of racism, and increase treatment use to increase smoking abstinence.

2.4. Study setting and participants

Participants will be recruited across the Minnesota region from rural and urban community-based health systems serving BIPOC communities. Participants will be recruited from primary care clinics at Hennepin Healthcare and the Mayo Clinic Health System (MCHS). Patients who currently smoke cigarettes will be identified in the EHR for remote and in-person recruitment. For remote recruitment, potential participants meeting eligiblity criteria will receive an invitation letter from their health system, introducing the study and offering an opportunity to opt-out of being contacted by calling a toll-free number or returning an opt-out form by mail. We will follow-up the invitation letter with a telephone call for futher explanation of the study and invitation to enroll. Interested participants will complete an eligibility screen and, if eligible, informed consent and HIPAA authorization will be remotely obtained and subsequently documented electronically using REDCap (link sent via email). An option to mail and return a signed paper version of the consent and HIPAA authorization form will also be provided. After documention of informed consent is received, participants will be asked to complete a baseline survey using REDCap. An option to compete the baseline survey over the telephone will be provided. For in-person recruitment, clinic staff will introduce the study to patients and gauge interest. If the patient is interested, study staff will meet potential participants at the clinic to describe the study and conduct the eligibility screening. If the participant is eligible, they will have the option of completing informed consent and baseline survey at that time or completing at a later time either remotely or in-person. Note that the LPO intervention will be completed by phone, even for those patients that are recruited in person.

Inclusion criteria include English or Spanish-speaking BIPOC primary care patients of Hennepin Healthcare or MCHS, resident of Minnesota, of any gender, $\geq$18 years, smoked cigarettes at all, even a puff, over the past 30 days, and with an address and a telephone number in the EHR. Exclusion criteria include: EHR documented cognitive impairment or legal guardianship and patients who have opted-out of research studies.

2.5. Randomization

Following completion of the baseline survey, eligible participants will be randomly assigned to condition using a 1:1 ratio with a blocked randomization scheme, stratified by the healthcare system (Hennepin Healthcare or MCHS) with randomly permuted blocks of size 2, 4, and 8 generated by the study statisticians, in a sequential manner unknown to study staff or the participants prior to randomization. Study staff conducting outcomes assessment and processing will be blinded to intervention assignment.

2.6. Interventions

2.6.1. Quit Partner Minnesota™

Both AAC and LPO have been designed to connect participants to Quit Partner Minnesota™ and/or the smoking cessation treatment programs of the participating health systems. Quit Partner™ is a family of programs available to help Minnesota residents quit commercial tobacco, administered by the Minnesota Department of Health (MDH). Quit Partner™ programs are provided by National Jewish Health (NJH), a large, non-profit Quitline provider. When individuals are connected with Quit Partner™, coordinators at NJH conduct an intake and determine eligibility. Minnesota residents can access a free 2-week supply of Nicotine Replacement Therapy (NRT) and are connected to free one-on-one telephone quit coaching (in English, Spanish, or third-party interpreter available for other languages). Quit Partner™ also offers population-specific programs (e.g., American Indian Quitline, a behavioral health program, and a program for pregnant and postpartum women). Asian language-speaking smokers can be transferred to the national Asian Smokers Quitine for in-language services. With the Quit Partner™ electronic referral, patients' names are sent to NJH. NJH makes up to five call attempts to reach each referred patient, with the first outreach attempt happening within 24 h of the referral confirmation. Patients are then connected to the Quitline program supported by their health insurance provider, if applicable, or the appropriate Quit Partner™ program. Quit Partner™ provides patient outcome data to the referring clinic (e.g., enrollment status, or number of calls completed).

2.6.2. Enhanced Usual Care (Ask-Advise-Connect)

AAC is increasingly being adopted into usual care but is not yet currently implemented at the participating sites. At Hennepin Healthcare and the MCHS, the 5A's [12] are the current standard of care and it is required to assess smoking status for every patient at every visit. In the proposed Enhanced Usual Care intervention, clinic staff will be trained to implement AAC. Specifically, staff will be trained to ask all patients if they smoke, document smoking status in the EHR, advise patients to stop smoking, and complete an electronic referral to Quit Partner™ or the health system's smoking cessation treatment program(s).

Clinic staff implementation strategy. At both study sites, new order smartsets have been created to allow providers to order smoking cessation medication, refer to on site tobacco cessation clinics, and refer patients to the quitline. At Mayo Clinic Health system, the smartset will be introduced during leadership meetings and an instructional video and written job aid will be disseminated by leadership. A reminder will be sent at the time of study launch by clinic leadership. At Hennepin Health System, the study PI will attend primary care clinic meetings and provide a 10-min presentation on Ask-Advise-Connect including how to order smoking cessation treatment. Upon study launch, a clinical champion (Clinic Medical Director) will attend primary care meetings and introduce the smartset. Job aids on how to use the smartset will be emailed to providers by clinic leadership.

2.6.3. Longitudinal Proactive Outreach (LPO)

Personalized Mailed Invitation Materials with Tailored Messages. Participants randomized to LPO (intervention) receive a welcome packet in their preferred language- Spanish or English. The personalized packet includes a welcome letter, LPO brochure describing the types of tobacco treatment services available from their health system with the dates of their next outreach calls, Quit Partner™ flyer, study-branded magnet and pen, and ClinCard for study payments. We will tailor these resources in collaboration with the C2DREAM Community Engagement (CE) Core and include messages culturally and linguistically tailored to BIPOC communities, guided by the literature on culturally adapting evidence-based interventions [29]. To help participants access the available treatment, the tailored materials will include instructions for participants interested in discussing their smoking to call the Quit Partner™ number to speak with a smoking cessation quit coach. They will also be informed that they will receive a phone call with more information about resources for smokers. Drawing on theoretical advances in health communication, the invitation materials will include tailored messages to enhance persuasive appeal and deliver motivational encouragement for smokers to seek treatment to quit smoking, since health communication messages specifically designed to be

relevant for a particular subgroup are more persuasive, and more effective at increasing smoking cessation and changing health behaviors than untailored messages [30,31]. These personalized invitation materials, developed in our prior work [32,33], will be further refined in community engagement studios and other engagement strategies utilized by the C2DREAM CE core. The materials will provide tailored messages addressing barriers to use of treatment, such as lack of knowledge about the safety, efficacy and functional benefits of pharmacotherapy, and the importance of family [13]. The materials will also address smokers who are not ready to quit right now but who want more information about treatment options and products that make it easier to quit [13].

Motivational Interviewing Outreach Calls. One week after the written materials are sent, only participants assigned to this condition will receive LPO by a MI-trained coach. The MI outreach call protocol will consist of 6 contact attempts over two weeks. In prior work, we successfully contacted 65–73 % of participants [34–36]. The MI outreach call protocol will be repeated at 3, 6, and 9 months for a total of four outreach cycles because participants may not have quit or may have relapsed. The protocol will allow participants to communicate that they "already quit" to stop calls until the next time interval or to be removed from the call list.

The purpose of the outreach calls is to: 1) enhance motivation to quit smoking, 2) promote self-efficacy, 3) encourage participation in smoking cessation treatment, and 4) provide information on the safety, efficacy, and functional benefits of pharmacotherapy, particularly NRT. However, both willingness to engage in this type of discussion and receptivity to treatment-relevant information is variable. Thus, in contrast to confrontational approaches frequently used by clinicians, coaches will employ MI techniques with consideration for the participant's level of readiness to quit [37]. For example, the coach would ask, "Can we talk about your smoking behavior to see what services might be best for you now or in the future?" Then the coach would assess the participant's readiness to quit smoking [38]. The content for the call will be tailored to the smoker's readiness to quit, and self-efficacy along with individual concerns about quitting. Because MI uses a patient-centered, autonomy-emphasizing approach, rapport is more easily established, especially among those not highly motivated to quit. Our findings from focus groups with low-income and BIPOC patients who smoke, who had negative experiences with being "told" to quit or "scared" into quitting, support this approach [13]. In our prior work with BIPOC communities, we tailored the standard MI approach to fit the needs of these populations [32,33]. Participants expressing interest in receiving smoking cessation treatment will be electronically referred to quit partner, provided assistance obtaining medication through their primary care provider or pharmacy, or referred to in-person treatment, based on patient preference. The majority of our target patient population has Medicaid, which covers NRT without a copay. Medication will be recommended for participants for both cessation and reduction goals. If the participant is not interested in NRT, counselors will discuss other FDA-approved medications and refer them to their primary care or health system's smoking cessation treatment provider.

LPO Counselor training and fidelity. The LPO intervention team will consist of trained tobacco treatment specialists including a bilingual counselor to provide treatment in Spanish. The LPO intervention team is part of the research team and is outside of the clinic. Counselors will have completed an accredited tobacco treatment specialist training program and motivational interviewing training from a certified trainer. Counselors will meet weekly with intervention team supervisors that include a certified tobacco treatment specialist trainer and a tobacco cessation clinic director for supervision. An internal medicine physician will also be available as needed for consultation about smoking cessation medication questions. Counselors will be trained on the protocol and 100 % of audiotapes will be monitored for fidelity until the counselors are proficient. Following this, 10 % of audiotapes will be monitored for fidelity by the tobacco cessation clinic director and 10 % of these will be double coded by a second investigator for assessment of interrater reliability.

2.7. Data sources and data collection

Study assessments will be administered in English and Spanish (participant preference) see Table 1. The questions used in the Spanish language surveys have been previously validated in Spanish or were transcreated by professional Spanish language interpreters and evaluated using cognitive interviews working with our community partners. Participants will complete 4 assessments over 18-months: at baseline, 6-, 12-, and 18-months post-enrollment. We will use the REDCap data management platform to administer and manage surveys. Survey links will be sent via email or text (participant preference). Those who do not respond and those without the capacity to receive text or emailed surveys will be called by a bilingual study staff member blind to condition and offered the opportunity to complete follow-up surveys by phone. Participants will be paid $20 per assessment (up to $80 total), and for those combustible tobacco abstinence at 18 months an additional $50 if they complete biochemical verification (regardless of the result). Participants will be informed at enrollment that individuals may be selected to complete a saliva sample or CO test but will not be told why they were selected.

2.7.1. Effectiveness measures

2.7.1.1. Primary intervention outcome. Smoking abstinence. Following recommendations from the Society for Research on Nicotine and Tobacco workgroup, the primary outcome is biochemically verified 7-day point prevalence cigarette abstinence at 18 months post enrollment [39]. We will verify self-reported abstinence using expired air carbon monoxide (CO) as breath CO measurement can verify abstinence from combustible tobacco products within the previous 24 h and is not confounded with detection of non-combustible tobacco or nicotine products. Those with a CO of <6 ppm will be considered abstinent [40]. We will mail these participants a kit containing the iCO™ Smokerlyzer®, a portable breath CO monitor that connects to a smartphone or tablet. The iCO™ (Bedfont® Scientific Ltd) has been validated against the medical grade Bedfont Smokerlyzer®. Participants will provide a breath sample and email the result.

As an alternative approach for those unable to use the iCO or for whom CO results would be invalid (e.g., those who smoke marijuana), we will verify self-reported smoking abstinence using salivary cotinine, the principal metabolite of nicotine, at the 18-month follow-up. Patients with cotinine levels <10 ng/ml will be considered abstinent.

2.7.1.2. Secondary intervention outcomes. Cessation behavior. We will assess self-reported six-month prolonged abstinence, defined as not smoking >5 cigarettes in the prior 6-months [39]. We will also assess self-reported 7-day point prevalence abstinence, as well as use of e-cigarettes and other nicotine/tobacco products at each follow-up period [39]. Duration of quit attempts during the intervention period will also be assessed.

Treatment utilization. We will assess self-reported utilization of EBCT during the 18-month follow-up from any source. The main treatment outcome will be initiation of counseling with Quit Partner™ or the patient's healthcare provider, combined with medication treatment utilization (e.g. bupropion, varenicline, NRT). Initiation of counseling treatment with the Quit Partner™ will be defined as completion of a warm transfer or electronic referral to the Quitline. Initiation of medication treatment will be defined as using one or more tobacco dependence medications (e.g., NRT, bupropion or varenicline) in the 18-month follow-up period. Additional treatment utilization outcomes include individual use of counseling or medication and use of any form of EBCT (counseling and/or medication). As a supplemental measure of

Table 1
Measures and assessment schedule.

	T0	6M	12M	18M	Data source	Measure
Demographics (race, ethnicity, sex, gender, sexual orientation, marital status, education, employment, insurance, English proficiency, household size, income, birthplace)	x				Survey	PhenX [44]
Structural/social determinants of health	x				EHR	Area Deprivation Index [45–50]
Sense of Community		x			Survey	Brief Sense of Community Scale [51]
Health literacy	x				Survey	Single Item Literacy Scale [52]
Daily/non-daily	x				Survey	CDC
Menthol use	x					California Tobacco Survey [54]
CPD/TTFC	x	x	x	x		HSI [56]
Other tobacco product use	x					California Tobacco Survey [54]
Financial strain	x				Survey	Keiser Permanente's YCLS Survey [57]
Other social and economic needs (perceived health/ functional status, alcohol use, social isolation & connection, housing situation, transportation, medication/ medical supply access, access to help with day-to day activities, and stress)	x					Keiser Permanente's YCLS Survey [57]
Healthcare access	x					NHIS [58]
Food access	x					USDA 6 item SFFSSM [59]
Disability	x					BRFSS [60]
Provider A-A-C	x	x	x	x	Survey	HEDIS Measures [70]
Contacts w/ healthcare system	x	x	x	x	EHR	EHR
Discrimination in medical settings	x				Survey	Discrimination in Medical Settings Scale [62–68]
Satisfaction with care	x					Patient Satisfaction Questionnaire [71,86]
7-day point prevalent abstinence		x	x	x	Survey	Self-report [39]
Biochemical verification of abstinence				x	Cotinine/ CO	Cotinine/CO [40]
6M prolonged abstinence		x	x	x	Survey	Piper [39]
Quit attempts	x	x	x	x		California Tobacco Survey, BRFSS [54,55]
Initiation of Quitline (AAC)				x	Survey and EHR	EPIC referrals; Quit Partner feedback report
Initiation of Quitline (LPO)				x		Study counselor records in Redcap; Quit Partner feedback report
Pharmacy				x		EHR
NDC/TCC				x		EHR
Medication use	x	x	x	x		Self-reported use of 7 FDA-approved meds
Medication Use				x		EHR data on prescriptions
Other resources (counseling, etc)	x	x	x	x		Self-report
Combined Quitline/Med use		x	x	x		Self-report/EHR/ Quit Partner records
Any EBCT use		x	x	x		Self-report/EHR/ Quit Partner records
Self-reported health	x			x		EQ-5D [41]
Quality of life	x			x		PROMIS 10, PHQ2 [42,43]
Structural racism	x				Public Data/ Survey	MMSR [72–74]
Daily discrimination	x				Survey	Everyday Discrimination Scale [75,76]
Global self-efficacy	x	x	x	x	Survey	Confidence in quitting scale [79,80]
Attitudes about quitting	x	x	x	x		Importance in quitting scale [79,80]
Readiness to quit/ remain quit	x	x	x	x		Readiness to quit ladder [81,82]
Friends and family who smoke	x					California Tobacco Survey [54]
Home smoking rules	x					

EBCT utilization, we will extract pharmacy claims data from the EHR and examine the prescription rates of individual medications, number of medications prescribed, and duration of medication use.

Quality of Life. Health-related quality of life will be assessed using the EuroQol- 5 Dimension (EQ-5D), which is a non-condition specific measure of health status across five dimensions of health [41]. Additionally, the PROMIS Global 10 will assess physical and emotional health, satisfaction with social activities and relationships, functionality, pain, fatigue, and overall quality of life [42]. Finally, the PHQ2 will assess frequency of depressed mood and anhedonia in the past 2-week period [43].

2.7.1.3. Background and control variables. Demographics. PhenX measures will be used to assess, biological sex, gender, sexual orientation, race/ethnicity, marital status, educational attainment, employment status, annual household income, household size, health insurance coverage, US nativity, years in the US, and English proficiency [44]. The Area Deprivation Index (ADI) assesses community determinants of health and incorporates indicators of income, education, employment and housing quality [45–50]. Age will be assessed using EHR data.

Perceptions of one's community. The 8-item Brief Sense of

Community Scale will assess participants' needs fulfillment, group membership, influence, and shared emotional connection with their community [51].Health literacy. Two single-item literacy questions will be used to evaluate limited health-related reading comprehension [52]. One will assess need for help comprehending written health-related materials, while the other assesses confidence in filling out medical forms [53].

Smoking history. Items from the California Tobacco Survey [54] and the CDC Behavioral Risk Factor Surveillance Survey [55] will assess, the duration of past quit attempts, prior use of tobacco treatment, as well as type of cigarette usage (menthol vs. non-menthol). The Heaviness of Smoking Index (HSI) will be used to assess participants' average number of cigarettes smoked per day and time until first cigarette after waking [56].

Current Life Situation. Items from the Kaiser Permanente's Your Current Life Situation (YCLS) will be used to evaluate other social and economic needs [57]. The items assess financial strain (trouble paying for basic needs), perceived health/functional status, alcohol use, social isolation & connection, housing situation, transportation, medication/medical supply access, access to help with day-to day activities, and stress. Access to healthcare services will be measured using items from the National Health Interview Survey (NHIS) Adult Access to Health Care & Utilization Module, including frequency of visits, type of health services utilized, hospitalizations, and delay/cost-related concerns about healthcare [58]. The USDA Six-Item Short Form Food Security Survey Module will be used to assess access to food and food insecurity [59]. Disability status will be assessed using 2 items from the Behavioral Risk Factor Surveillance System [60]. Frequency and duration of physical activity will also be assessed [61].

Healthcare provider factors. Experiences of discrimination in the healthcare setting will be measured with the Discrimination in Medical Settings Scale [62–68] as well as a single-item item healthcare discrimination item (i.e. "Was there ever a time if you belonged to a different ethnic or racial group?") [69]. HEDIS tobacco performance measures [70] will assess participants' receipt of smoking cessation advice (AAC), as well as their overall satisfaction with the smoking cessation care they have received from their healthcare provider [71] We will extract the number of primary care visits from the EHR.

2.7.1.4. Potential moderators. Structural racism will be assessed using the Multidimensional Measure of Structural Racism (MMSR) [72–74]. Experiences of day-to-day discrimination will be assessed using the 9-item Everyday Discrimination Scale, which is a subscale of the Perceived Discrimination Scale (PDS) that captures participants' experiences with unfair treatment in their day-to-day lives [75,76].

2.7.1.5. Potential mediators. Smoking-specific constructs from The Theory of Planned Behavior (TPB) will be assessed as potential mediators of the intervention effect [77,78]. Perceived behavioral control toward smoking cessation will be assessed using the single item confidence in quitting scale, which is scored from 0 to 10 with higher scores indicating greater confidence in quitting/remaining quit [79,80]. We will assess intentions to quit/remain quit using the Readiness to Quit Ladder, which is scored from 0 to 10 with higher scores indicating greater readiness to quit [81,82]. Attitudes toward cessation will be assessed using the importance of quitting scale, which is derived from the confidence in quitting scale [80,83]. Social environment will be assessed by asking participants to report the proportion of their family/friends who smoked and their rules for smoking within the home [54].

2.7.2. Implementation evaluation measures

Feasibility and acceptability of AAC and LPO will be measured 3 ways:

Surveys. We will survey clinic medical directors and clinic managers to assess for acceptability of the intervention to the healthcare system and will administer the, the Acceptability of Intervention Measure, the Intervention Appropriateness Measure, and Feasibility of Intervention Measure, and the Organizational Capacity to Implement Change Measure at the beginning and end of patient data collection [84,85]. To assess patient acceptability of the intervention, we will administer to study participants the 8-item Client Satisfaction Questionnaire at the 18 month follow-up survey assessment [86].

Administrative data. We will use medical record data to assess facilitation including the proportion of patients with smoking status documented and, of those who reported smoking, the proportion who were counseled and referred for treatment (prescribed medicines or referred to internal or external smoking cessation programs).

Semi-Structured Interviews. We will conduct semi-structured interviews of 10–12 primary care staff and 10–12 patients assigned to the LPO condition. Interviews will assess the acceptability of study interventions, the acceptability of the implementation of those interventions, and tools or support needed for future implementation of the interventions within the healthcare system. Staff interviews will also assess their perspectives of how LPO may be integrated (e.g., within the clinic or as part of a centralized hub program). Patient interviews will also assess experiences of bias in the delivery of treatment by the quitline and/or local cessation services.

2.7.3. Sample size and power analysis

Sample size calculations consider power for analysis of biochemically verified 7-day smoking abstinence at 18-months. Prior research has found 7-day biochemically verified abstinence under AAC of approximately 5 %. Past proactive outreach trials have found treatment effects ranging from 2.6 % to 7 % for prolonged abstinence. We feel a robust treatment effect of around 5 % is most plausible given the longitudinal nature of the intervention which features additional follow-up calls at 3, 6, and 9 months. Assuming a .05 significance level and a 70 % participant retention/biochemical verification response rate, enrolling 2000 participants (1000 per arm) will provide 95 % power to detect a significant difference in biochemically verified 7-day point prevalence abstinence rates at 18 months (primary intervention outcome) across treatment arms. Power is 79 % or greater across alterations to the assumed quit rate under AAC (4 %–6 %) and changes to the effect of AAC + LPO (4 %–5.5 % increase in quit rate relative to AAC).

2.7.4. Analyses

Analysis of study aims will use an intent-to-treat approach. The randomized design should confer covariate balance across intervention arms. To assess balance, we will evaluate bivariate associations between intervention condition and relevant baseline covariates and between each covariate and the outcomes. Any unbalanced baseline covariates will be included in covariate adjusted versions of the planned analyses.

2.7.4.1. Aim 1 analyses. To evaluate the direct effect of the intervention on the dichotomous intervention outcomes at the 18-month month follow-up (biochemically verified smoking abstinence, EBCT utilization, use of e-cigarettes, use of other nicotine/tobacco products), simple proportions will be computed for each treatment arm including 95 % confidence intervals. Outcomes will then be modeled using logistic regression to estimate and test intervention effects. Causal inference will be based on point estimates of the odds ratio for the effect of AAC + LPO on the outcome relative to AAC, along with 95 % confidence intervals, and corresponding likelihood ratio test results. For the continuous outcomes (QOL), standard linear regression will be used. For non-binary outcomes (frequency of quit attempts), models will be fit with appropriate distribution and link functions to match the form of the data.

In addition to the main analysis described above, we will also employ longitudinal analyses of the intervention outcomes using generalized linear mixed models. Specifically, we will use mixed effects logistic

regression models to assess the effect of the intervention on the dichotomous study outcomes across the 6-, 12-, and 18-month time points. These models will include random effects for the intercept and time (varying across individuals) and fixed effects for the intercept, intervention, and intervention by time interaction term. This longitudinal analytic approach will be used to evaluate the extent to which treatment effects differ at 6, 12, and 18 months. The approach will be used to evaluate the treatment main effect as well as a treatment by time interaction. A mixed model, longitudinal analytic approach will also be used in the analysis of the continuous and non-binary study outcomes. These models will be fit with appropriate distribution and link functions to match the distribution and nature of the data.

2.7.4.2. Aim 2 analyses. We will assess structural racism (MMSR index) and daily interpersonal discrimination (EDS) as potential moderators of the effect of AAC + LPO on trial outcomes. As the moderating factors of interest will not be randomly assigned to treatment groups, there is the potential for confounding to bias the estimates of the interaction effects. Our inferential analysis will therefore be based on a modified propensity analysis, whereby we will adjust for any observed covariate imbalance between subgroups of patients at differing quintiles of the moderating factors of interest (cut-offs at the 0, 25, 50, 75, and 100th percentiles). For the primary outcome analysis, we will use propensity-adjusted logistic regression to model the log odds of biochemically verified abstinence as a function of intervention, MMSR quintile, and their interaction. If a statistically significant interaction is observed, we will proceed with stratified logistic regression analyses to examine the effect of the intervention on trial outcomes separately within each subgroup.

2.7.4.3. Aim 3 analyses. We will report descriptive statistics of the patient Client Satisfaction Questionnaire, the Organizational Capacity to Implement Change, the Acceptability of Intervention Measure, the Intervention Appropriateness Measure, and the Feasibility of Intervention measure. Using a structured debriefing form, post-interview notes will be written after each interview and reviewed. Interviews will be professionally transcribed and deidentified. Two independent investigators will develop analytical codes using an iterative method in which notes are reviewed to: 1) consider whether the qualitative research agenda questions are appropriate and complete, 2) whether content saturation has been reached, and 3) develop an initial coding structure. Deductive codes will be drawn from the interview questions; inductive codes will capture concepts that emerge from the interviews. Once the coding scheme is developed, two investigators will independently code transcripts and meet to resolve discrepancies. Final codes will be entered into NVivo qualitative analysis software and we will conduct a framework matrix analysis to identify the most effective ways to organize content to guide future implementation efforts [87,88].

2.7.4.4. Exploratory analyses. A mediated moderation analytic framework will be used to explore whether improvements in perceived behavioral control and intentions to quit/remain quit are responsible for the intervention effects. We will test the hypothesis that the positive effects of the intervention will be stronger for patients with higher (vs lower) experiences with discrimination in healthcare settings at baseline, and that these effects will be mediated by greater increases in perceived behavioral control (confidence in quitting scale) and intention to quit/remain quit (Readiness to Quit Ladder), assessed at baseline, 6-, 12-, and 18-months, among patients in AAC + LPO vs AAC. These analyses will estimate indirect (mediational) effects, or the extent to which changes in patients' confidence in quitting and intention to quit/remain quit following delivery of the intervention affect likelihood of abstinence. The final stage of analysis will employ moderated mediation analyses examining how mediation effects vary with the moderator, e.g., subgroups with higher vs lower discrimination, to explore differences in the causal mechanisms affecting smoking outcomes.

2.7.4.5. Non-response and missing data. Due to possible differential non-response between the two treatment arms, we may lose the covariate balance between survey respondents. As such, we will compare respondents in the two arms with respect to key elements of the conceptual model and baseline measures a priori known to be related to tobacco cessation. If the two conditions are found to differ with respect to these relevant pre-intervention variables, then these variables will be included as covariates in the respective analyses. These analyses will be used to inform investigators of the nature of the missing data mechanism.

If the above analyses find some component of the missing data to be missing at random, we will repeat the primary analysis with multiple imputations of the missing survey data for the formulation of the abstinence outcome under the assumption the data is missing at random. We will develop a logistic regression model to impute the missing survey data using abstinence status at 6, 12, and 18 months, intervention group, gender, and other baseline information as explanatory measures. Multiple imputation methods will use this logistic regression model to impute 50 imputed complete datasets, apply the primary analysis described above to each imputed dataset, and aggregate results using standard methods for multiple imputation analyses.

To assess the potential impact of outcome data assumed to be missing not at random we will implement a series of selection models using the methods of Ibrahim and Lipsitz [89]. These analyses will specify the same logistic regression model for the outcome as described above and model observance of the outcome, or selection into the observed sample, using a logistic regression model with abstinence status, intervention group, gender, and other baseline information as explanatory measures. The results of these analyses are dependent upon the form of selection model employed so we will investigate a range of selection models considering various interactions between outcome value, intervention, and the other explanatory variables to assess the impact of potential nonignorable missingness across a range of potential mechanisms.

3. Summary

The SCORE trial tests two chronic care model interventions for tobacco cessation induction amongst BIPOC primary care patients. Ask-Advise-Connect is a systems level intervention that relies on providers to address smoking and refer patients to the Quitline and/or local smoking cessation services. Longitudinal proactive outreach works at the individual level to reach out to patients who might not otherwise have smoking addressed. Longitudinal proactive outreach, while more labor intensive and costly for the health system, has the capacity to counteract systemic racism in healthcare settings by reaching out to those in most need of care. This trial will advance research into chronic care interventions for smoking cessation by: (1) being one of the largest trials of a smoking cessation intervention for BIPOC patients, (2) testing proactive outreach to connect patients to community and health system resources for tobacco cessation, (3) testing the mechanisms of change of an intervention intended to promote health equity, and (4) testing the potential of chronic care approaches to be implemented into medical settings serving BIPOC patients.

CRediT authorship contribution statement

Steven S. Fu: Writing – original draft, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization. **Patrick Hammett:** Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis. **David Nelson:** Writing – original draft, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Andrew Busch:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Warren McKinney:** Writing – review & editing, Methodology. **Pravesh Sharma:** Writing – review & editing, Investigation. **Christi A. Patten:** Writing – review & editing, Supervision, Project administration, Investigation, Funding acquisition. **Nathalia Gutierrez Sacasa:** Writing – review & editing, Project

administration, Data curation. **Lynn Andreae:** Writing – review & editing, Supervision, Project administration, Data curation. **Sandra Japuntich:** Writing – original draft, Supervision, Project administration, Investigation, Funding acquisition, Conceptualization.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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