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ORIGINAL ARTICLE

Patient Perspectives in Cardiovascular Research: A Qualitative Study of Barriers, Trust, and Strategies for Inclusive Clinical Trials

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BACKGROUND: Women, Black, and Hispanic patients bear a disproportionate burden of cardiovascular disease yet remain underrepresented in clinical trials. Understanding patient perspectives is essential to developing inclusive recruitment strategies in cardiovascular research.

METHODS: The RECHARGE trial (Revascularization Choices Among Underrepresented Groups Evaluation) is an ongoing comparative effectiveness study comparing percutaneous coronary intervention and coronary artery bypass grafting among women, Black, and Hispanic patients. To inform recruitment strategies, we conducted a qualitative study using in-person and virtual focus groups and semistructured interviews. Participants were US adults who identified as Black or Hispanic and had a history of percutaneous coronary intervention, coronary artery bypass grafting, or advanced cardiovascular disease. Interviews were guided by the Social-Ecological Model and analyzed using directed content analysis with a constant comparative approach.

RESULTS: The sample included 42 participants (35 women, 7 men); 29 identified as Hispanic and 13 as Black. Barriers and facilitators to trial participation spanned multiple levels of the Social-Ecological Model. At the individual and interpersonal levels, barriers included complex study materials, excessive medical jargon, and mistrust of randomization, with concerns about being assigned a less effective treatment. At community and societal levels, participants cited limited recruitment outreach, lack of culturally and linguistically appropriate materials, and mistrust stemming from historical research injustices. Facilitators included trust in healthcare providers, reassurance regarding treatment appropriateness, and involvement of family or support systems. At the community and societal levels, accessible, visual, and multilingual materials were highlighted to support understanding. Participants emphasized the value of plain language, visual, and multilingual materials, adequate time for shared decision-making, and transparent communication about study goals.

CONCLUSIONS: Increasing representation of underrepresented populations in cardiovascular trials requires transparent, accessible communication and trust-centered recruitment strategies. Leveraging trusted healthcare providers and community-based outreach is critical to advancing equity in cardiovascular research.

REGISTRATION: URL: https://www.clinicaltrials.gov; Unique identifiers: NCT06399705 and NCT06399692.

Key Words: cardiovascular diseases ■ clinical trials ■ coronary artery bypass ■ minority groups percutaneous coronary intervention

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What Is Known

- Major cardiovascular randomized clinical trials, including percutaneous coronary intervention versus coronary artery bypass grafting studies, have predominantly enrolled non-Hispanic White men.
- Black and Hispanic patients experience a high burden of cardiovascular disease, yet remain underrepresented in cardiovascular research, limiting the generalizability of trial findings.

What The Study Adds

- This study presents patient-informed insights from Black and Hispanic adults regarding barriers to and facilitators of participation in cardiovascular randomized clinical trials, including trials comparing percutaneous coronary intervention and coronary artery bypass grafting.
- Participants identified physician endorsement, clear explanations of randomization and its clinical rationale, and inclusion of family or support systems as central to informed trial participation.
- Findings highlight the value of using visual and easy-to-understand communication approaches to build trust, improve understanding, and support engagement in cardiovascular research.

Nonstandard Abbreviations and Acronyms

CABG	coronary artery bypass grafting
CVD	cardiovascular disease
EXCEL	Effectiveness of Left Main Revascularization)
PCI	percutaneous coronary intervention
RCT	randomized controlled trial
RECHARGE	Revascularization Choices Among Underrepresented Groups Evaluation Randomized Controlled Trial
SEM	Social-Ecological Model
SYNTAX	Synergy Between PCI With Taxus and Cardiac Surgery

Coronary revascularization trials have historically enrolled predominantly non-Hispanic White men, creating a critical gap in understanding the outcomes of percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) among women, racial, and ethnic minority groups.[1–3] Women, Black, and Hispanic patients are disproportionately affected by cardiovascular disease (CVD) and often experience worse outcomes after revascularization with both procedures.[4,5] Despite representing the largest racial and ethnic minority groups in the United States, Black and Hispanic individuals remain underrepresented in cardiovascular research, limiting the evidence available to guide their prognosis and treatment decisions for PCI and CABG.[6,7]

The lack of representation reflects a longstanding and systemic problem in cardiovascular research.[8,9] In a review of 178 cardiovascular randomized controlled trials (RCTs) conducted from 1998 to 2017, only 42.7% reported race data, and the enrollment of Hispanic (11.2%), Black (4%), and female (28.3%) participants was much lower than the proportions of these groups with CVD.[10,11] Even recent landmark PCI versus CABG trials, including the EXCEL (Effectiveness of Left Main Revascularization) and SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) trials, enrolled only 22% to 28% women.[12–14] These persistent disparities raise concerns about the generalizability of trial findings and underscore the need for studies that more accurately reflect real-world patient populations.

Understanding the factors driving underrepresentation is essential to improving recruitment in clinical trials. Research across multiple disciplines has identified individual, interpersonal, and structural barriers that contribute to low participation in research among underrepresented populations.[15,16] One major barrier is trust, shaped by longstanding medical injustices and ongoing systemic inequities.[17] Trust, in the context of research, is a multifaceted construct encompassing perceptions of ethical conduct, transparency, cultural respect, and protection from harm.[18,19]

The RECHARGE (Revascularization Choices Among Underrepresented Groups Evaluation) RCT aims to address this critical gap by evaluating the comparative effectiveness of PCI and CABG by enrolling only women, Black, and Hispanic patients for whom clinical equipoise exists.[20] To inform recruitment strategies before trial initiation, we conducted focus groups with Black and Hispanic individuals with a history of PCI, CABG, or advanced CVD. The objective of this qualitative study was to identify patient-reported facilitators and barriers to cardiovascular research participation to improve the inclusivity and accessibility of the RECHARGE trial and inform future related trials.

METHODS

Ethics Statement

This study was reviewed and approved by the institutional review board at Columbia University. Participants provided verbal informed consent and received an information sheet outlining the study.

Conceptual Framework

We used the Social-Ecological Model (SEM) as a guiding framework to examine the multilayered barriers and facilitators to clinical research participation.[16] The SEM conceptualizes behaviors as shaped by interactions across individual, interpersonal, community or organizational, and societal and has been widely applied to study social and structural influences on research participation.[16,21,22] In this study, the SEM informed theme identification and organization across these levels.

Study Design

This was a prospective, exploratory qualitative study that sought to identify barriers and facilitators to cardiovascular clinical trials among racial and ethnic minority populations to inform inclusive enrollment strategies in the RECHARGE trial. Participants were not enrolled in RECHARGE. Individual interviews and focus groups were conducted with adults with a history of coronary revascularization or advanced CVD. Data were analyzed using a thematic approach, and the final codebook may be made available from the corresponding author on reasonable request.

Study Participants

Eligible participants were individuals aged 45 years to 75 years with prior PCI, CABG or a history of advanced CVD who self-identified as Black or Hispanic, spoke English or Spanish, and were able to provide informed consent. Participants were recruited through the Washington Heights/Inwood Infrastructure for Community-Centered Comparative Effectiveness Research Project,[23,24] Columbia University Medical Center's RecruitMe network,[25] and the RECHARGE Patient and Stakeholder Advisory Board to facilitate recruitment beyond New York City.[26] Recruitment concluded when thematic saturation was reached.[27]

Interview Guide

The interview guide (Supplemental File 1) was developed with input from the RECHARGE Patient and Stakeholder Advisory Board, which was chaired by a patient with lived experience of PCI and CABG and included community leaders, health educators, cardiac surgeons, cardiologists, nurses, hospital administrators, and researchers. The guide explored participants' experiences with PCI and CABG, perceived barriers and facilitators to clinical trial participation, perspectives on enrollment in a randomized trial comparing PCI and CABG, and the types of information that would support informed decision-making for participation. The study adhered to the Consolidated Criteria for Reporting Qualitative Research guidelines (Supplemental File 2).

Data Collection

Interviews were conducted via Zoom between February 2024 and June 2024, consisting of 13 focus groups and 11 individual interviews. Focus groups ranged from 2 to 4 participants. Interviews were conducted in English or Spanish by a trained, bilingual Certified Health Education Specialist with qualitative research experience and lasted 40 to 60 minutes. All sessions were audio-recorded and transcribed verbatim using a HIPAA-compliant transcription service. Field notes were taken during interviews to enhance dependability. Participants received a $75 gift card as compensation.

Data Analysis

Four members of the research team (a Hispanic female, Master's degree researcher; a Hispanic female research assistant with a Bachelor's degree, a Hispanic male research assistant with a Bachelor's degree, and an Asian male undergraduate public health student) analyzed transcripts using NVivo 12 software. Spanish-language interviews were translated into English using a HIPAA-compliant service and independently reviewed for accuracy by 2 bilingual team members before analysis. Inductive content analysis was used to identify common themes.[28]

All transcripts were independently coded by at least 2 of 4 coders, and coding discrepancies were resolved through weekly iterative discussions, and consensus on themes and subthemes was reached collaboratively.[29] A codebook was developed based on the interview guide and refined through the double-coding process (Supplemental File 3). Methodological triangulation was achieved by incorporating data from both focus groups and individual interviews, and investigator triangulation was supported by a multidisciplinary analytic team.

Themes were subsequently organized as barriers or facilitators and mapped to the SEM across 4 levels. Individual-level themes reflected participants' knowledge, beliefs, and attitudes toward research, including understanding of randomization. Interpersonal themes captured the influence of family members, friends, and healthcare providers. Community and organizational themes reflected experiences with healthcare institutions and research practices, whereas societal-level themes addressed broader cultural norms, values, and policies shaping attitudes toward clinical trial participation.

RESULTS

The study sample included 42 participants (35 females, 7 males) with a mean age of 62.8±8.1 years. Of these, 29 self-identified as Hispanic, and 13 as Black. Participants had a history of PCI (n=13), CABG (n=6), both procedures (n=6), or advanced CVD (n=22). Most were from New York State (n=33, 76%); 2 participants were from California, and 1 participant each was from North Carolina, Florida, Texas, New Jersey, Tennessee, and Virginia. Table 1 summarizes the participants' demographic characteristics.

Qualitative Results

Across interviews and focus groups, we identified 7 barriers and 9 facilitators to cardiovascular trial participation spanning the 4 levels of the SEM (Figure 1).

Patient-Identified Barriers to Engaging Cardiology-Related Clinical Trials

Barriers across the SEM reflected an interplay of mistrust in research practices, complex communication, and limited accessibility of research within underrepresented communities (Table 2).

Individual Level: Unclear Explanation of Randomization Contributes to Hesitancy

Skepticism about randomization and generalization was prevalent, as participants expressed wanting personalized

Table 1. Self-Identified Demographic Characteristics of the Interview Sample

Demographic characteristic	Overall (N=42)
Age, y (mean, SD)	62.8 (8.1)
Sex, n (%)	
Female	35 (83.3)
Male	7 (16.7)
Self-identified race, n (%)	
Black	13 (31.0)
White	29 (69.0)
Self-identified ethnicity, n (%)	
Hispanic or Latino origin	29 (69.0)
Primary language, n (%)	
English	16 (38.1)
Spanish	26 (61.9)
CVD history or surgery	
PCI	13 (31.0)
CABG	6 (14.3)
CABG and PCI	3 (7.1)
No surgery, but has advanced CVD	20 (47.6)
History of stroke, n (%)	
No	37 (88.1)
Yes	5 (11.9)

CABG indicates coronary artery bypass grafting; CVD, cardiovascular disease; and PCI, percutaneous coronary intervention.

approaches that address their treatment needs. Some participants believed that treatment assignment in RCTs was influenced by socioeconomic status or insurance coverage, raising concerns about receiving a "worse" treatment.

> *"It does depend on your insurance. It depends on what you can pay for what they will give you…If you can afford open heart surgery, and they can give you a stent, you are about to get your chest cracked open. That's just the bottom line."—73-year-old Hispanic female*

Interpersonal Level: Inaccessible Communication Hinders Engagement and Understanding

Participants described prior clinical encounters in which procedures were explained using dense medical jargon that did not account for varying levels of health literacy. Often, participants mentioned that medical jargon creates a perception that providers prioritize technical expertise over the "human side of the equation," leaving them feeling undervalued. They also raised concerns about transparency and wanted reassurance from their providers that both procedures were appropriate options within an RCT.

Community Level: Limited Outreach and Supportive Research Efforts

Participants highlighted challenges related to accessibility and representation, noting that research often feels inaccessible to their communities, that racial minorities are excluded, and that there is little follow-up or support after data collection.

> *"But one problem with a clinical trial that I am aware of is a lot of times, when the trial is over, there is no follow-up or there is no coverage for the people that were in it."— 62-year-old Hispanic male*

Societal Level: Historical Mistrust and Systemic Inequities

Many participants voiced concerns about historical mistreatment and systemic inequities, highlighting that

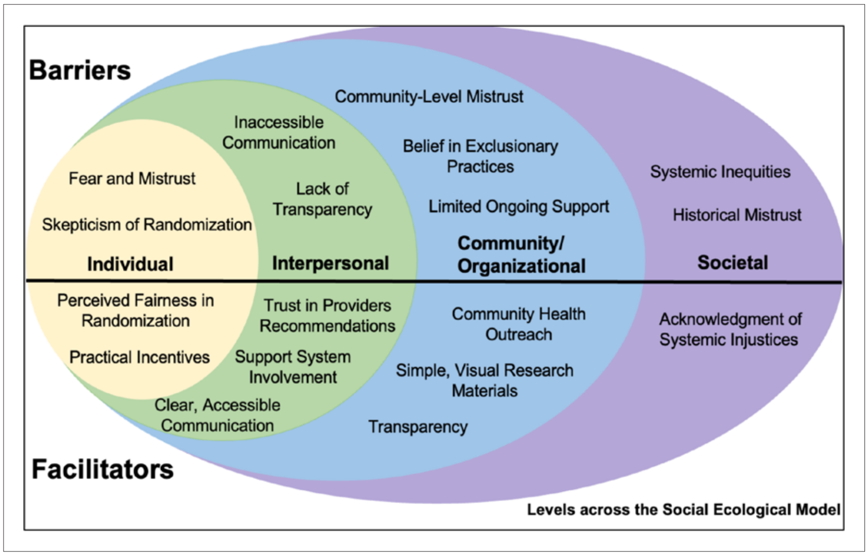


Figure 1. Multilevel barriers and facilitators to trial participation.
Barriers and facilitators to participation in a randomized trial comparing coronary artery bypass grafting and percutaneous coronary intervention, organized across individual, interpersonal, community/organizational, and societal levels of the Social-Ecological Model.

Table 2. Participant-Identified Barriers to Engaging in Cardiology-Related Research

SEM level	Barriers	Illustrative quotes
Individual	Skepticism of randomization in research	“No. Randomization doesn’t work because we are different, we are unique and that takes that part out of it completely. There are different treatments our body reacts certain ways differently, and to do everything randomized in a sense, if everybody is on an equal playing field, but we are not. It’s not equal.”—45-year-old Black female
		“It does depend on your insurance. It depends on what you can pay for what they will give you…If you can afford open heart surgery, and they can give you a stent, you are about to get your chest cracked open. That’s just the bottom line.”—73-year-old Hispanic female
Interpersonal	Inaccessible communication	“They are still thinking of it from their end and that’s probably hard, because you are asking somebody with this high medical degree…they’ve got to understand how you would think… they are so hammered with data that they are ignoring the human side of the equation, so to speak, and I think that’s why a lot of people say no.”—62-year-old Hispanic male
		“Because different people have different dialects, different words mean different things to different people… Okay, just because we speak Spanish doesn’t mean that all of us speak the same Spanish, and English is a very difficult language.”—73-year-old Hispanic female
	Lack of transparency	Some clinics, they are not transparent in what they are doing. This causes a mistrust between the clinic and the participants.”—45-year-old Black male
Community/ Organizational Level	Community-level mistrust	“The randomization and open-heart surgery, it’s just… we are fearful of the outcomes that have happened based off the past and I think before you can do those types of studies and trials you will have to build trust in the community. You have to go in the community to be part of the community before you can do that, because I’ve lost a lot of trust. I think that has to be done first.”—52-year-old Black female
		“I would think about it. Because science has advanced a lot and scientists are very intelligent, they choose the weakest person to be part of the study.”—65-year-old Hispanic female
	Belief in exclusionary practices	“I think their upbringing has a lot to do with it. So, unless those kids grow up in an environment where they can network with people who are more knowledgeable than they are, then those who are less educated are overlooked. Nobody reaches out to them because they don’t have the credentials that some people feel they need to have.”—73-year-old Hispanic female
		“ They prefer to provide study opportunities to Americans… and people of color and Hispanics are treated as minorities.”—68-year-old Hispanic female
	Limited ongoing support	“But one problem with a clinical trial that I am aware of is a lot of times, when the trial is over, there is no follow-up or there is no coverage for the people that were in it.”—62-year-old Hispanic male
Societal	Historical mistrust and systemic inequities	“We’ve been guinea pigs and we are guinea pigs because everything that they give us is not something that they know”—65-year-old Hispanic female
		“It just goes back to using humans as guinea pigs and giving them things that they should not have been giving to them because that’s not what they were told they were given, and just being deceitful. That’s created such a big area of mistrust and that’s not in the back of a person’s mind if they are African-American, that’s in the front of your mind. So, when people are talking about doing research, no, you are not going to use my body for research.”—57-year-old Black female

SEM indicates Social-Ecological Model

past unethical practices contribute to ongoing mistrust of research institutions and fears of being treated as “guinea pigs.” Explicit mentions of mistrust in research were most frequently cited by Black participants, with some describing historical mistreatment as a major barrier to trusting their providers’ guidance on revascularization options. Many expressed a strong desire for providers to acknowledge this history and adopt comprehensive communication practices.

> *“[Researchers] giving them things that they should not have been giving to them because that’s not what they were told they were given and just being deceitful. That’s created such a big area of mistrust, and that’s not in the back of a person’s mind if they are African American—that’s in the front of your mind. So, when people are talking about doing research, no, you are not going to use my body for research.”—57-year-old Black female*

Patient-Identified Facilitators to Engaging Cardiology-Related Clinical Trials

Facilitators of research emphasized promoting engagement and trust within minoritized communities through provider advocacy for trial participation, involvement of support systems in decision-making, providing transparent and accessible research materials, and acknowledgment of historical injustices in research (Table 3).

Individual Level: Practical Incentives Encourage Participation

Participants identified financial compensation as a practical facilitator that helped offset time and logistical burdens. Some also viewed randomization positively, describing it as a fair process that reduced provider bias in treatment assignment.

> *"I strongly believe that a clinical trial that's done this way leaves less of an opportunity for the doctors to have control of who goes into the study, who receives for instance a placebo or an actual drug, or an actual procedure. I think if it's left to chance, the opportunity for a positive outcome is greater."—61-year-old Black male*

Interpersonal Level: Trust in Providers and Family Support

Trust in healthcare providers was described to strongly influence their willingness to participate, particularly when clinicians took time to explain procedures, answer questions, and engage patients with respect and patience. Some participants expressed greater willingness to participate when research participation was recommended by a trusted provider.

> *"With the knowledge that either option would be in my best interest, and with the help of my doctor, I wouldn't have a problem making a choice."–75-year-old Black female*

This perspective was also commonly noted among Hispanic participants, who underscored the importance of personal connections with healthcare providers and the involvement of family or support systems before deciding to enroll in a study.

> *"I would talk to my family first before making a decision."—65-year-old Hispanic female*

Community Level: Accessible Materials and Transparent Communication

Participants emphasized the need for community-centered outreach efforts and transparent communication about research validity, purpose, and risks.

> *"I would want some data, if you are going to present to me… Some track record, …of both procedures. Why the research is being done. Why is it being looked at. What are the potential shortfalls, what are the potential benefits, that kind of stuff."—62-year-old Hispanic male*

Simplified, visual materials, such as videos and interactive models, were highlighted as effective tools for enhancing understanding.

> *"I think a clear visualization [would be helpful] ….Information more than just on a piece of paper. Something that's concrete that I can understand."—62-year-old Hispanic male*

Societal Level: Acknowledgment of Historical Injustices is Crucial for Trust

Participants emphasized that acknowledging systemic inequities and historical medical injustices is essential for rebuilding trust in research, particularly through healthcare institutions taking ownership of past injustices.

> *"It's about trust, but I am going to take it a level higher…. So, on some level, at a national level, it's acknowledging and owning the past, repenting for the past and really working with community leaders."—56-year-old Black female*

Implementation of Participant-Centered Strategies in the RECHARGE Trial

Findings from the focus groups were directly integrated into the RECHARGE trial's recruitment strategies. These strategies were organized around 4 patient-identified priorities: randomization, communication and transparency, recruitment and support, and trust-building. As shown in Figure 2, each priority informed specific, actionable strategies to enhance participant engagement. The RECHARGE Stakeholder Advisory Board played a central role in ensuring that these efforts reflected the real-world patient perspectives and priorities identified in this study.

To improve understanding of randomization, study materials were developed using plain language to explain the process, emphasize physician oversight and clinical equipoise, and clarify that treatment assignment is not based on demographic characteristics. To enhance communication and transparency, we clarified the criteria for participant outreach, emphasized the routine use of CABG and PCI in clinical practice, and reinforced the role of participants' own healthcare providers in the study recommendation process. Insights regarding the importance of physician-led recommendations for participation and family involvement also informed site trainings, with the goal of creating more opportunities for shared decision-making during recruitment.

Recruitment materials explicitly addressed the historical underrepresentation of diverse populations in cardiovascular trials and highlighted the value of participant contributions. Trust-building efforts included multilingual, visually accessible materials shaped by patient input and explicit acknowledgment of past underrepresentation to foster confidence in the research process. Examples of our institutional review board–approved recruitment materials, including, infographics, brochures, and patient videos designed to accommodate different learning styles, are provided in Supplemental File 4.

Table 3. Participant-Identified Facilitators to Engaging in Cardiology-Related Research

SEM level	Facilitators	Illustrative quotes
Individual	Belief in fairness in randomization process	"I strongly believe that a clinical trial that's done this way leaves less of an opportunity for the doctors to have control of who goes into the study, who receives for instance a placebo or an actual drug, or an actual procedure. I think if it's left to chance, the opportunity for a positive outcome is greater."–61-year-old Black male
	Practical incentives	"The socio-economics about it. The fact that we are busy and some of us are single parents. There are a lot of barriers when it comes to time…If there is an incentive to make sure that we are there, that could be an option. So, it has to be incentivized."–45-year-old Black female
Interpersonal	Trust in providers recommending research participation	"With that knowledge of the fact that either one of them would be to my best interest, with the help of my doctor, and because of that and because of my relationship… Then I wouldn't have a problem making a choice."–75-year-old Black female
		"I want to see [my doctor] and I know that she can talk me down, bring me down, have that attention to say, yes, even though you are being firm, I allow you to be firm with me because I believe you, what you're saying"–70-year-old Black female
	Clear, accessible communication	"What I noticed about her [the physician] is that when I go into her office and I have questions, she does not mind answering my questions…if she uses technical terms she will break it down for me and explain to me what's going on. She doesn't try to rush me out of her office. I felt like in the hospital, when I was trying to talk to this guy, he would try to rush out of my room and I got no answers."–57-year-old Black female
	Family/support system involvement in decision-making process	"I would meet with my family and see what they think. If they say the surgery is better, although my life might be in danger, I'll do it."–68-year-old Hispanic female
		"I have gathered my family and looked for different doctors that conduct that procedure [PCI] for my heart to avoid having to do surgery"–65-year-old Hispanic female
Community/ organizational	Community health outreach	"A lot of times, people don't participate in things because they don't know it exists. So, finding different channels, community-driven channels that allow people to have that access to those things, because I think a lot of times, there may not be people like me who have those reservations. There may be people who are interested in it, but they just don't know that it's available to them."–52-year-old Black female
		"Go to community centers or churches where many of us gather, and, for instance, announce at Church that there will be a talk to provide information about what will be done with us. It's very important to inform people."–65-year-old Hispanic female
	Transparency	"I would want some data, if you are going to present to me, about scientific data… Some track record, and I don't know if I'm saying it right, of both procedures maybe. Why the research is being done. Why is it being looked at. What are the potential shortfalls, what are the potential benefits, that kind of stuff."–62-year-old Hispanic male
	Simple, visual research material	"I think a clear visualization… If you have the model, you can open it and take it, and show over here. Information more than just on a piece of paper. Something that's concrete that I can understand."– 63-year-old Hispanic male
Societal	Acknowledgment of systemic inequities	"It's about trust, but I am going to take it a level higher. America did a disservice to our community on a number of fronts. Where I see the tide turning is ownership of the past; acknowledging and admitting that there is a history of mistrust. I mean, it's rightfully so, a founded history of mistrust, but at some point, and I don't know what the correct organization or the agency is but public health agency…So, on some level, at a national level, it's acknowledging and owning the past, and really working with community leaders."–56-year-old Black female

PCI indicates percutaneous coronary intervention; and SEM, Social-Ecological Model.

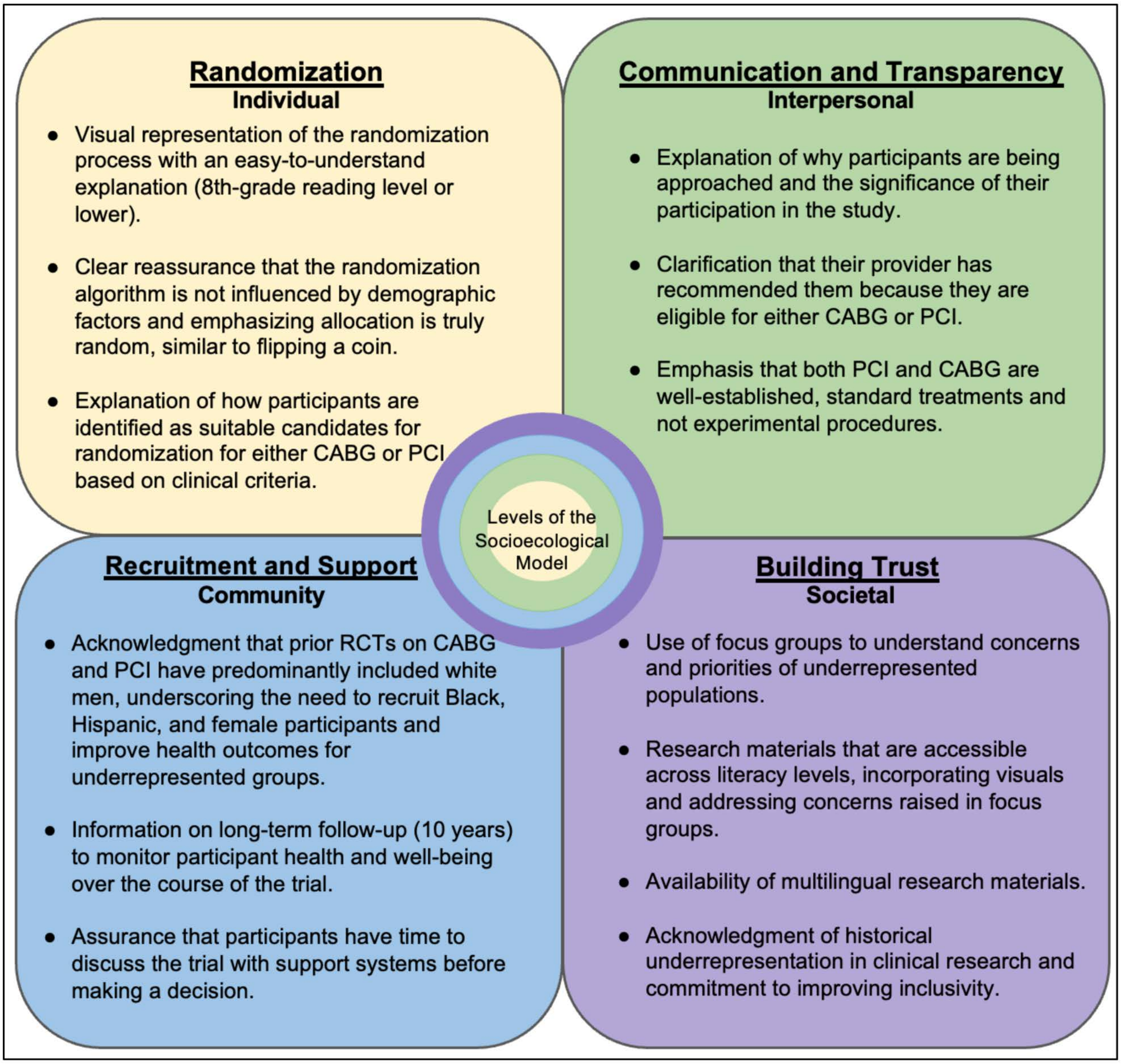
DISCUSSION

In this prospective qualitative study, we identified patient-reported barriers and facilitators to participation in a cardiovascular RCT. Our findings provide actionable insights for improving engagement in future cardiovascular trials, including the RECHARGE trial, which is uniquely positioned to address a critical evidence gap by enrolling underrepresented racial and ethnic minorities for whom clinical equipoise exists between PCI and CABG.

Barriers to Engagement in Cardiovascular Clinical Research

Participants described multiple barriers to trial participation, particularly related to recruitment materials, randomization, and structural access. Many found traditional informed consent documents overly complex, lengthy, and filled with medical jargon, contributing to confusion and disengagement, especially among individuals with lower health literacy.[30,31] Several participants reported feeling overwhelmed by unclear explanations from providers, underscoring the need for intentionally accessible and patient-centered communication. Without intentional modifications to enhance accessibility, traditional methods risk alienating individuals who might otherwise be open to participation.

Participants expressed both positive and negative views of randomization. Some questioned whether assignments to PCI or CABG were truly random, suspecting external influences such as insurance coverage. Hesitancy toward randomization has also been reported in previous studies,[17,32,33] and often related to concerns about historical injustices and unethical research practices.[34–36] Conversely, some participants viewed randomization as a way to reduce provider bias in treatment



Randomization
Individual

- Visual representation of the randomization process with an easy-to-understand explanation (8th-grade reading level or lower).
- Clear reassurance that the randomization algorithm is not influenced by demographic factors and emphasizing allocation is truly random, similar to flipping a coin.
- Explanation of how participants are identified as suitable candidates for randomization for either CABG or PCI based on clinical criteria.

Communication and Transparency
Interpersonal

- Explanation of why participants are being approached and the significance of their participation in the study.
- Clarification that their provider has recommended them because they are eligible for either CABG or PCI.
- Emphasis that both PCI and CABG are well-established, standard treatments and not experimental procedures.

Recruitment and Support
Community

- Acknowledgment that prior RCTs on CABG and PCI have predominantly included white men, underscoring the need to recruit Black, Hispanic, and female participants and improve health outcomes for underrepresented groups.
- Information on long-term follow-up (10 years) to monitor participant health and well-being over the course of the trial.
- Assurance that participants have time to discuss the trial with support systems before making a decision.

Building Trust
Societal

- Use of focus groups to understand concerns and priorities of underrepresented populations.
- Research materials that are accessible across literacy levels, incorporating visuals and addressing concerns raised in focus groups.
- Availability of multilingual research materials.
- Acknowledgment of historical underrepresentation in clinical research and commitment to improving inclusivity.

Figure 2. Participant-informed recruitment strategies in the RECHARGE trial (Revascularization Choices Among Underrepresented Groups Evaluation)

. Participant-informed strategies to improve engagement in the RECHARGE trial, mapped across socioecological levels and focused on randomization education, transparent communication, community engagement, and trust-building. CABG indicates coronary artery bypass grafting; PCI, percutaneous coronary intervention; and RCT, randomized controlled trial.

decisions. These findings suggest that explanations of randomization should explicitly address how the process minimizes selection bias and clarify that demographic or insurance factors do not determine treatment assignment.

Structural barriers to recruitment were another key theme, with many participants noting that underrepresented groups are often excluded from clinical research invitations. This further highlights the need for research teams to prioritize outreach strategies that build trust and demonstrate commitment to inclusion, ensuring equitable opportunities for historically overlooked populations.[29–37] Additionally, sharing study results with participants after the trial is complete is an opportunity to build trust.

Facilitators for Increasing Representation

Clear, transparent communication was consistently identified as a key facilitator to enhance comprehension. Participants recommend incorporating visual aids to explain certain concepts, such as randomization. For example, a coin flip has frequently been used to illustrate randomization,[38] but some participants found this analogy uncomfortable in the context of invasive cardiovascular procedures. They suggested pairing such visuals with a clear explanation emphasizing that both PCI and CABG are appropriate, evidence-based options. Multilingual materials and describing the societal benefits of participation and its potential to advance equity in cardiovascular care were also viewed as motivating.[38,39]

Support Systems in Decision-Making

Many participants emphasized the importance of having support systems when making medical decisions, noting that family members would influence their willingness to enroll in a trial. Allowing adequate time for discussion with support systems before asking potential participants to decide may improve recruitment, consistent with prior research demonstrating the benefits of family engagement in research participation.[40,41]

Proactively Working Toward Building Trust in Research

Most participants recommended that acknowledging historical injustices and explaining how trials like RECHARGE address these inequities is essential for building trust. Consistent with prior studies, our participants expressed skepticism about the intentions and ethical safeguards of clinical trials.[35,42–44] Several participants noted that learning about the lack of representation in previous RCTs comparing PCI and CABG would help them understand why a study like RECHARGE is needed. Therefore, clearly describing efforts to address these gaps may encourage participation and emphasize that diverse populations are essential contributors to representative medical evidence.

Although historical injustices have shaped mistrust, ongoing disparities in healthcare access, communication, and treatment can continue to reinforce these concerns.[45] Addressing trust must involve not only acknowledging past harms but also actively confronting present-day inequities in research. Evidence-based strategies such as partnering with trusted community organizations, employing culturally concordant staff, and prioritizing transparent, patient-centered communication are critical to rebuilding trust in clinical research.[46]

Trust building also requires proactive engagement beyond initial recruitment. Participants highlighted the importance of ongoing communication and sharing study results, approaches shown to improve recruitment, retention, and trust.[19,47] Investing in long-term engagement may lower recruitment costs and enhance inclusivity.[48–50] Practical considerations, including compensation, transportation, and flexible scheduling, were also identified as essential for improving trial accessibility among historically excluded populations.

In response to these findings, the RECHARGE trial incorporated participant-informed strategies to improve inclusivity and accessibility, including simplified, visually oriented, and multilingual recruitment materials. These adaptations were designed to address concerns related to communication, randomization, and trust, and reflect a commitment to integrating patient perspectives into trial design.

Limitations

This study's findings may have limited generalizability as participants were primarily from one US region. Although the interview guide was developed with broad advisory input, some relevant concerns may have been missed. The focus on women and Black and Hispanic patients may not capture barriers faced by other underrepresented groups or settings. Although bilingual reviewers checked translations, some cultural nuances might have been lost, introducing potential bias. Lastly, the impact of the tailored recruitment materials developed from these findings has not yet been assessed.

Conclusions

Reducing disparities in cardiovascular research requires a comprehensive, equity-focused approach that acknowledges historical inequities, improves accessibility, and builds trust with underrepresented communities. Our findings highlight the importance of recruitment strategies that extend beyond traditional outreach by prioritizing clear communication, transparency, and cultural responsiveness. Incorporating these participant-identified strategies into the RECHARGE trial and future studies is essential to achieving equitable representation in cardiology clinical studies.

ARTICLE INFORMATION

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Disclosures

None.

Supplemental Material

Supplemental Files 1–4

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