



## Original Research

## The Equity Deficit in Revascularization Research: Patient Perspectives Emphasize the Need for Inclusive, Patient-Centered Outcomes

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## ABSTRACT

**Background:** Randomized trials comparing coronary artery bypass grafting (CABG) with percutaneous coronary intervention (PCI) have historically underrepresented women, Black, and Hispanic patients. Moreover, primary composite cardiovascular endpoints often fail to reflect the outcomes most important to patients, such as symptoms, function, and quality of life (QoL). The Revascularization Choices Among Underrepresented Groups Evaluation (RECHARGE) trial of PCI vs CABG addresses this gap by enrolling only women, Black, or Hispanic patients and incorporating death and QoL as a hierarchical primary endpoint tested by the win ratio. To inform RECHARGE's patient-centered design, qualitative interviews with patients to develop recruitment strategies and to elicit their treatment priorities.

**Methods:** We conducted a prospective qualitative study involving 13 focus groups and 11 individual interviews with 42 adults (ages 45-75 years) who had cardiovascular disease with or without a prior PCI or CABG. Participants self-identified as Black or Hispanic and were recruited through academic and community networks. Interviews were conducted in English or Spanish, transcribed, and thematically analyzed using directed content analysis. Recruitment continued until thematic saturation.

**Results:** Participants (83% women; 69% Hispanic; 31% Black) expressed 3 key themes: (1) limited understanding of cardiovascular disease and feeling dismissed by providers; (2) prioritization of QoL, independence, and recovery in treatment decisions; and (3) concerns about randomization in clinical trials, driven by mistrust and a need for clearer, culturally responsive communication.

**Conclusions:** Patients from underrepresented groups prioritize functional recovery and trust in research engagement. These findings directly informed RECHARGE's inclusive recruitment and highlight strategies to advance equity-focused, patient-centered cardiovascular research.

## Introduction

Clinical evidence from randomized controlled trials (RCTs), such as those comparing coronary artery bypass grafting (CABG) with percutaneous coronary intervention (PCI), guides decision making in the treatment of cardiovascular disease (CVD). The evidence base from these trials has overwhelmingly reflected the outcomes in non-Hispanic White men, leaving significant gaps in understanding how the outcomes of alternative revascularization strategies may differ

among historically understudied populations, including women, Black, and Hispanic patients.<sup>1-3</sup>

The Revascularization Choices Among Underrepresented Groups Evaluation (RECHARGE) trial represents a significant shift in cardiovascular research design.<sup>4</sup> It is the first multicenter RCT comparing CABG with PCI to enroll exclusively women, African American or Black (henceforth referred to as Black) or Hispanic patients, with coprimary outcomes of just survival and patient-centered health status. Specifically, the primary outcome is a hierarchical composite of all-cause

Abbreviations: CVD, cardiovascular disease; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; QoL, quality of life; RCT, randomized controlled trial; RECHARGE, The Revascularization Choices Among Underrepresented Groups Evaluation Trial; REVASCHOICE, Revascularization Choices.

Keywords: coronary artery bypass; patient participation; percutaneous coronary intervention; qualitative research; trust.

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mortality and time-averaged quality of life (QoL) over 5 years, assessed when the last enrolled patient completes 3 years of follow-up. RECHARGE enrolls patients with left main or multivessel coronary artery disease for whom the local heart team determines that there is clinical equipoise for CABG or PCI. Through its inclusive design and focus on patient-centered outcomes, RECHARGE aims to generate more relevant and representative evidence for future women, Black, and Hispanic patients and their clinicians.

Past major trials comparing CABG and PCI have enrolled fewer than 25% of women and less than 5% of Black or Hispanic participants.<sup>5–8</sup> Moreover, to increase power and reduce trial size, these studies have largely focused on composite cardiovascular endpoints, particularly major adverse cardiovascular and cerebrovascular events.<sup>7,9,10</sup> In addition, most trials have used time-to-first-event analyses that weigh all events in the composite equally, despite different components of composite outcomes having markedly different clinical importance.<sup>11</sup>

As such, traditional composite endpoints often fail to capture outcomes that patients prioritize, such as how they feel and function after treatment. Patient-reported outcomes (PROs), including physical and mental health, daily functioning, and QoL, provide a more patient-centered assessment of treatment benefit but have historically not been used as primary endpoints in revascularization trials.<sup>9,12</sup> Additionally, noncardiovascular consequences such as depression, fatigue, and difficulty returning to normal activities, which significantly affect patients' lived experiences, are often omitted entirely.<sup>13</sup>

Given the historic challenges in recruiting women, Black, and Hispanic participants, the RECHARGE team conducted a prospective, exploratory qualitative study to inform its patient engagement strategy and confirm the relevance of the primary outcome, called Revascularization Choices (REVASCHOICE). The objective of REVASCHOICE was to understand the lived experiences of women, Black, and Hispanic patients with CVD, particularly those who had undergone or were eligible for CABG or PCI, to identify key concerns, informational gaps, and patient-defined priorities to better guide participant recruitment and follow-up. These efforts generated important insights to potentially inform future clinical trials seeking to enroll more inclusive populations ([Central Illustration](#)).

## Materials and methods

### Study design and sample

This prospective, exploratory qualitative study aimed to understand the experiences and perspectives of underrepresented patients with CVD to inform inclusive, patient-centered engagement strategies for the RECHARGE trial. Eligible participants were adults aged 45 to 75 years who had a diagnosis of CVD or had previously undergone PCI or CABG. Additional criteria included the ability to speak English or Spanish and self-identification as Black or Hispanic.

Participants were recruited through the Washington Heights or Inwood Infrastructure for Community-Centered Comparative Effectiveness Research Project<sup>14,15</sup> (Hispanic participants), Columbia University Medical Center's RecruitMe<sup>16</sup> network (Black participants), and snowball sampling via the RECHARGE Patient and Stakeholder Advisory Board. Recruitment concluded upon reaching thematic saturation.

### Data collection

We conducted 13 focus groups and 11 individual interviews between February and June 2024 using Columbia University's secure, Health Insurance Portability and Accountability Act (HIPAA)-compliant

Zoom platform. All sessions were led by a trained, bilingual certified health education specialist with qualitative research experience. Interviews were conducted in English or Spanish using a semistructured guide ([Supplemental File 1](#)) developed with input from the RECHARGE Patient and Stakeholder Advisory Board, which includes patients, clinicians, researchers, and community stakeholders.

Interview topics included participants' knowledge of CVD, diagnostic experiences, understanding of PCI and CABG, outcomes influencing procedural decisions when choosing between CABG and PCI (eg, recovery time, symptom relief, and return to work), and their perspectives on potential recruitment and follow-up challenges to participating in a RCT comparing CABG with PCI. Interviews were audio-recorded, transcribed verbatim by a HIPAA-compliant service, and translated into English, when necessary. Field notes were recorded during each session. Participants received a \$75 electronic gift card for their time. The Standards for Reporting Qualitative Research checklist is provided in [Supplemental File 2](#).

### Data analysis

Data were analyzed using directed content analysis in NVivo 12 software (Lumivero). Four members of the research team independently coded the transcripts, with each transcript reviewed by at least 2 coders. Coding discrepancies were resolved through iterative team discussions. Spanish transcripts were translated into English prior to analysis. Two additional team members—a certified health education specialist and a researcher with extensive qualitative analysis experience—reviewed the codebook and emerging themes. They contributed to refining and finalizing the thematic structure. Recruitment continued until saturation was achieved and no new themes emerged. Consistent with reflexive thematic analysis, we did not quantify themes; qualitative prevalence terms were used to convey salience without implying statistical inference.

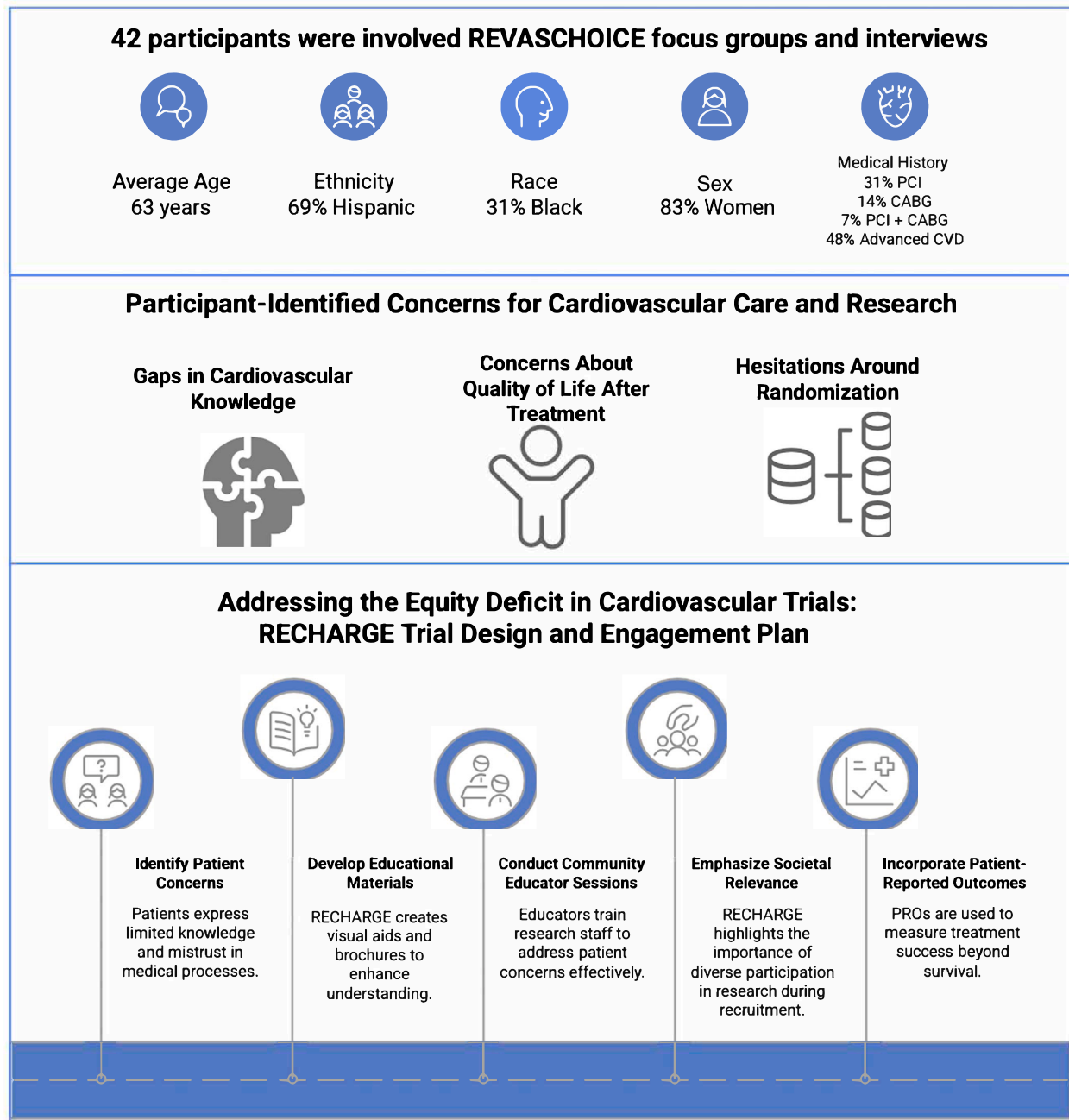
## Results

The sample included 42 participants: 35 women and 7 men. A total of 29 (69%) participants self-identified as Hispanic or Latinx and 13 (31%) as Black or African American. The mean age was  $62.8 \pm 8.1$  years. Thirteen participants had previously undergone at least 1 PCI, 6 had a history of CABG, and 3 had undergone both PCI and CABG. Twenty participants had not received revascularization but had advanced CVD. Five participants reported a history of stroke. Participant demographic and clinical characteristics are summarized in [Table 1](#).

Three recurring themes emerged, reflecting patients' experiences with CVD and their perceptions of revascularization treatment options, as follows: (1) gaps in patient knowledge, communication, and experience of being overlooked in cardiovascular care; (2) concerns about QoL and independence; (3) hesitations around randomization for CABG vs PCI.

### Theme 1: gaps in patient knowledge, communication, and experience of being overlooked in cardiovascular care

Many participants described having limited CVD knowledge prior to their diagnosis, including limited awareness about risk factors, how symptoms present, and who is typically affected. Some participants described clinical encounters where they felt dismissed, misunderstood, or excluded from decision making. The concepts contained within this theme, along with supporting quotations, are provided in [Table 2](#).

**Central Illustration.**

**REVASCHOICE participant demographics, key concerns, and the RECHARGE trial's engagement strategies to address equity in cardiovascular research.** CABG, coronary artery bypass graft; CVD, cardiovascular disease; PCI, percutaneous coronary intervention; PRO, patient-reported outcome.

*Limited awareness and misattributed symptoms*

Several participants reported limited knowledge of CVD and the risk factors associated with heart-related conditions prior to their diagnosis.

"I didn't have the information available to recognize [the symptoms], and I didn't bring it up to my doctors when I went, because I was justifying what it was at the time."—man, early 60s

Many shared that they misinterpreted early symptoms—such as chest pain, jaw discomfort, or fatigue—as indigestion or stress, which delayed care.

"My friend told me, 'You should go down to the emergency room,' and I said, no, it's just maybe an indigestion... There was a doctor next door... he said, 'Okay, I am going to send you to the emergency room.'"—woman, mid 70s

*Misconceptions about who is at risk*

A number of participants expressed shock at their diagnosis, noting that they did not see themselves as a typical cardiac patient. Many associated CVD with older White men and were surprised to learn they were at risk. One participant reflected on her active lifestyle and how that contributed to her disbelief:

**Table 1.** Demographic characteristics of participants from focus groups and interviews

Demographic characteristic	N = 42
Age, y	62.8 ± 8
Sex	
Female	35 (83)
Male	7 (17)
Self-identified race	
Black or African American	13 (31)
White	29 (69)
Self-identified ethnicity	
Hispanic or Latinx origin	29 (69)
Primary language	
English	16 (38)
Spanish	26 (61)
CVD history or surgery	
PCI alone	13 (31)
CABG alone	6 (14)
PCI and CABG	3 (7)
CVD with neither PCI nor CABG	20 (48)
History of stroke	
Yes	5 (11.9)
No	37 (88.1)

Values are mean ± SD or n (%).

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

"Cardiovascular disease was something that happened to old White men... I was in shape, I exercised, I was eating fairly well—I did not expect heart issues to be in my future."—woman, early 50s

#### Communication barriers and perceived clinical dismissal

Many participants described how medical jargon and rushed conversations made it hard to understand their condition or ability to participate meaningfully in decision making. A participant described how complex language increased her confusion, leading to her having many questions left unanswered:

"I know that when doctors go to school they learn those big words and when they are talking to the patients, sometimes they use those big words and you say what does that mean... if they would just explain it in the lowest definition, then that would alleviate all of the questions."—woman, early 70s

Others emphasized the importance of clear, transparent communication using layman's terms, including risks, benefits, and procedural details:

"I believe that perhaps a more concise understanding could be reached by the doctor explaining things in layman's terms, not medical terms, not doctor language. Explain to the patient what is going to go on, the benefits and the detailed risks. How many times has this been done?"—man, early 60s.

Spanish-speaking participants also emphasized the need for in-person explanations and family involvement to address language barriers. Several participants reported that their symptoms were not taken seriously until their condition escalated. One participant recalled feeling blamed for her condition and emotionally dismissed by her provider in the hospital:

"[The doctor] came in, in front of my family, saying, 'She is having a mild heart attack. This is related to stress. I told her that she needed to quit her job. I told her that she needed to lose weight.' Brought me back for another echocardiogram and while he was doing it I was crying. He was like, 'Why are you crying?' And I said, 'because I feel like you're not doing everything that you are supposed to do. I

just feel like there is something wrong and you've missed me'."—woman, mid 40s

One participant described how their family had to advocate for her to receive more care while in the hospital as they were attempting to discharge her:

"My sister came in and they were going to dismiss me, and she was like, 'No, something is wrong. You have to do the tests again... You cannot let her leave. She can't even move her leg and her arm'. So, she was persistent ... that's when everything kind of changed because that's when they did the second tests and they found that I had an ischemic stroke, but before that they were about to kick us out of the hospital"—woman, mid 50s

Several participants connected their individual experiences to broader patterns of inequity in cardiovascular care. Many felt that their race, sex, or age contributed to being overlooked or dismissed. One participant described the broader emotional toll of navigating the health care system as a woman of color with heart disease:

"I feel like the doctor is like a mechanic... I feel hopeless. Every day, this heart journey is different... and I think of those women who just don't know and just die. Their voices aren't being heard. Period."—woman, mid 40s

#### Recommendations for accessible cardiovascular education

Additionally, many participants described how their knowledge about CVD grew over time through provider interactions, self-directed research, and the use of visual tools. Visual learning tools were particularly helpful in bridging communication gaps; one Spanish-speaking participant described how an illustrated diagram and a video depicting stent placement helped her visualize and comprehend her treatment:

"Yes, they gave me a little figure, like an ID card. So, I could keep it, and they explained that it was to improve my health, to open up the artery... there was also a video with a heart. They showed the camera and the stent. It was like a little movie." —woman, mid 70s

#### Theme 2: concerns about QoL and independence in decision making

Participants consistently emphasized that treatment success was not defined solely by survival or other cardiac events but by their ability to return to daily routines, care for loved ones, and maintain independence. Illustrative quotes are provided in [Table 2](#).

##### Prioritizing QoL in decision making

When asked what they consider important when deciding between treatment options, many participants emphasized wanting to understand the full impact of a treatment beyond clinical risks, noting that they wanted to know how the procedures would affect their day-to-day lives.

One participant expressed his need for clarity about the functional consequences of a procedure if given the choice to decide:

"I would like to know if it's absolutely necessary for the surgery. I would like to know how long I'm going to be out of it. Am I going to be able to work?"—man, mid 60s

**Table 2.** Illustrative quotes of key themes

<b>Theme 1. Gaps in patient knowledge, communication, and experience of being overlooked in cardiovascular care</b>	
Limited awareness and misattributed symptoms	<p>"I knew that there were heart attacks, I knew that there were strokes, and I had heard of open heart surgery ... someone tells you that you're having a heart attack ... that's just what came to my mind because I was not educated on anything cardiac-related."—women, late 50s</p> <p>"My friend told me, 'You should go down to the emergency room,' and I said, no, it's just maybe an indigestion... There was a doctor next door... he said, 'Okay, I am going to send you to the emergency room.'"—woman, mid 70s</p> <p>"I didn't even know what she was talking about. I was like, what do you mean, and the minute I said, where are we going, I got a sharp pain on the left side of my jaw. It went straight down my shoulder to my arm and I knew something was wrong, but I didn't know it was a heart attack"—women, late 50s</p>
Misconceptions about who is at risk	<p>"Cardiovascular disease was something that happened to old White men... I was in shape, I exercised, I was eating fairly well—I did not expect heart issues to be in my future."—woman, early 50s</p> <p>"I know tons now, but when this first started for me, I didn't know anything. I had given birth five days before and I had a massive heart attack. I was thrust into this arena really unprepared. I was a young mother. I had two other children and then this new five-day-old baby and I had a massive heart attack"—woman, mid 50s</p>
Communication barriers and perceived clinical dismissal	<p>"Cardiovascular disease was something that happened to old White men... I was in shape, I exercised, I was eating fairly well—I did not expect heart issues to be in my future."—woman, early 50s</p> <p>"[The doctor] came in, in front of my family, saying, 'She is having a mild heart attack. This is related to stress. I told her that she needed to quit her job. I told her that she needed to lose weight.' Brought me back for another echocardiogram and while he was doing it I was crying. He was like, 'Why are you crying?' And I said, 'because I feel like you're not doing everything that you are supposed to do. I just feel like there is something wrong and you've missed me.'"—woman, mid 40s</p> <p>"My sister came in and they were going to dismiss me, and she was like, 'No, something is wrong. You have to do the tests again... You cannot let her leave. She can't even move her leg and her arm.' So, she was persistent... that's when everything kind of changed because that's when they did the second tests and they found that I had an ischemic stroke, but before that they were about to kick us out of the hospital"—woman, mid 50s</p>
Recommendations for accessible cardiovascular education	<p>"Yes, they gave me a little figure, like an ID card. So, I could keep it, and they explained that it was to improve my health, to open up the artery... there was also a video with a heart. They showed the camera and the stent. It was like a little movie."—woman, mid 70s</p> <p>"I went from my primary care physician to a physician there, and they showed you videos that say, for you, education for you. Yeah, so I learned a lot about that because he's put that information at my disposal."—woman, mid 60s</p>
<b>Theme 2. Concerns about QoL and independence in decision making</b>	
Prioritizing QoL in decision making	<p>"I would like to know if it's absolutely necessary for the surgery. I would like to know how long I'm going to be out of it. Am I going to be able to work?" —man, mid 60s</p> <p>"Because what matters most is not just quantity, but living with quality. A lot of people have many years, but I want to live with quality, not just quantity."—woman, mid 60s</p>
Fear of long-term dependence and disability	<p>"I immediately think of being dependent. If I am a dependent... that doesn't last as long as you may need, especially if it's ongoing and it's months and years, and I couldn't handle that because I love people too much to make them responsible for me." —woman, early 60s</p> <p>"Not being able to take care of things at home—my kids, my job, all of that worried me. Having to depend on someone else... It was a tough time in the hospital." —woman, mid 50s</p>
Anxiety about postoperative support and recovery	<p>"I had nobody to take care of me. They did not tell me when they cut you open you don't have any muscles anymore... I had to learn how to get out of bed. Nobody told me nothing, nothing." —woman, mid 60s</p> <p>"The wound leaked constantly... The dressings would have to be changed regularly. I was sent home with no wound care and no follow-up visiting nurse. I was sent home with no wound care and no follow-up visiting nurse. I couldn't do much for myself at that time, and my home was a wreck."—man, early 60s</p>
<b>Theme 3: Hesitations around randomization for CABG vs PCI</b>	
Concerns around randomization for CABG vs PCI	<p>"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 woman</p> <p>"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."—woman, mid 40s</p>

CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; QoL, quality of life.

Another participant, emphasized the difference between lifespan and life quality, describing that longevity without wellness was not her goal.

"Because what matters most is not just quantity, but living with quality. A lot of people have many years, but I want to live with quality, not just quantity."—woman, mid 60s

#### *Fear of long-term dependence and disability*

Participants also shared deep fears of losing their autonomy. For some, the thought of becoming dependent on others for prolonged or uncertain periods of time was concerning. A participant who underwent CABG reflected on the emotional weight of dependence:

"I immediately think of being dependent. If I am a dependent... that doesn't last as long as you may need, especially if it's ongoing and it's months and years, and I couldn't handle that because I love people too much to make them responsible for me."—woman, early 60s

Another worried about not being able to care for her family during her recovery:

"Not being able to take care of things at home—my kids, my job, all of that worried me. Having to depend on someone else... It was a tough time in the hospital."—woman, mid 50s

#### *Anxiety about postoperative support and recovery*

Some participants described being unprepared for recovery after receiving either a CABG or PCI, citing inadequate discharge education, lack of physical support at home, and insufficient follow-up care.

One woman described returning home alone after CABG, unaware of the physical limitations she would face:

"I had nobody to take care of me. They did not tell me when they cut you open you don't have any muscles anymore... I had to learn how to get out of bed. Nobody told me nothing, nothing."—woman, mid 60s

Another participant shared a particularly difficult experience of being discharged with an unhealed wound and no home health support:



"The wound leaked constantly... The dressings would have to be changed regularly. I was sent home with no wound care and no follow-up visiting nurse. I couldn't do much for myself at that time, and my home was a wreck."—man, early 60s

### Theme 3: hesitations around randomization for CABG vs PCI

Many participants expressed skepticism toward clinical trials, particularly regarding the concept of randomization. Although some acknowledged the value of research, there was broad concern that RCTs overlooked individual differences in patients' bodies, circumstances, and needs. Several participants expressed fears that demographic factors such as race, income, and insurance status might still influence treatment allocation.

"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."—woman, early 70s

Another participant voiced concerns that the randomization process might overlook individual needs and inequities:

"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."—woman, mid 40s

## Discussion

This qualitative study explored the lived experiences of women, Black, and Hispanic patients with CVD, focusing on how they understood their diagnosis, evaluated treatment options, and viewed RCTs in the context of CABG vs PCI. Participants included individuals who had previously undergone coronary revascularization and those managing advanced disease, offering a broad range of perspectives across different stages of care. The findings not only shed light on barriers shaping cardiovascular care but also directly informed the design of the RECHARGE trial to make it more inclusive and patient centered.

*Insights from theme 1: what patients know, need, and experience in cardiovascular care*

**What we learned.** Many participants described limited foundational knowledge about CVD and available treatments prior to diagnosis. Symptoms such as fatigue, jaw pain, or arm discomfort were frequently misattributed to stress or indigestion, leading to delays in care. Several participants expressed surprise at their diagnosis, often due to the belief that CVD primarily affects older White men. Communication challenges further exacerbated these gaps, with participants describing rushed clinical interactions, unfamiliar medical terminology, and limited opportunity to ask questions. Some relied on family members to advocate for their care, whereas Spanish-speaking participants highlighted the need for language-concordant, in-person communication, as often experienced in clinical settings.<sup>17</sup> These experiences left patients feeling dismissed, confused, and unprepared to navigate complex treatment decisions.

**How RECHARGE is responding.** In response to these patient-identified concerns, RECHARGE incorporates strategies to foster understanding, trust, and engagement during the recruitment process.

Traditional research materials frequently are not sensitive to lower health literacy levels and do not incorporate visual aids, but many participants highlighted how essential this was for improving comprehension.

Feedback from this study helped inform the design and content of these materials, which include the following: (1) a visual infographic explaining study risks, benefits, the randomization process, and the importance of research participation among women, Black, and Hispanic populations; (2) a trifold brochure that addresses key concerns raised by participants, such as postprocedural recovery and decision-making uncertainty; and (3) videos featuring diverse patient experiences with CVD. The institutional review board–approved recruitment material can be found in [Supplemental File 3](#). All materials were written at or below an eighth-grade reading level to support accessibility and are also available in Spanish. These materials use clear language and visual aids that are inclusive of diverse patient experiences, helping individuals see themselves reflected in the research process, improve understanding of their disease, and seek to demystify clinical trials, in particular for populations historically underrepresented in research.

Importantly, the recruitment process is structured to give patients time to review materials, ask questions, and consult with loved ones before deciding—which has also been suggested as a recommendation in previous work.<sup>18–20</sup> By providing early, comprehensible education and framing participation as a choice that can contribute to more inclusive cardiovascular evidence, RECHARGE aims to reduce confusion, challenge misconceptions, and ensure that patients feel informed and empowered throughout the process.

*Insights from theme 2: redefining what also matters QoL after treatment*

**What we learned.** Participants emphasized that the success of treatment was not defined solely by survival but by the ability to return to their routines, care for family members, and live independently. Many described anxiety about the recovery period, including fears of dependence, emotional distress, and inadequate postdischarge support. Some were unprepared for the physical limitations they experienced following procedures, whereas others described insufficient follow-up care or lack of assistance at home. Participants valued their QoL above specific adverse major adverse cardiovascular and cerebrovascular event outcomes such as stroke, myocardial infarction or repeat revascularization during follow-up, which were rarely mentioned. These insights reinforce the limitations of traditional composite cardiovascular endpoints in capturing what patients' value most.<sup>21</sup>

**How RECHARGE is responding.** To better reflect what also matters to patients, RECHARGE redefines treatment success by incorporating PROs in a hierarchical primary endpoint of all-cause mortality and improvement in QoL, the latter time averaged during 5-year follow-up (ie, QoL during each month of follow-up counts equally). PRO tools capture physical, emotional, cognitive, and functional aspects of recovery. The specific PRO instrument that is being used in the RECHARGE primary endpoint is the Short Form 12v2,<sup>22</sup> to assesses overall health and well-being. The Seattle Angina Questionnaire<sup>23</sup> is a disease-specific PRO measure that focuses on symptoms and angina-related physical limitations and QoL. Additional measures include the Patient-Reported Outcomes Measurement Information System 29<sup>24</sup> and the Montreal Cognitive Assessment,<sup>23,25</sup> to provide a more complete picture of recovery that is aligned with patients' real-world priorities.

### Insights from theme 3: proactively address concerns about randomization

**What we learned.** Mistrust of the randomization process emerged as a meaningful barrier to participation for several patients. Some questioned whether assignments to PCI or CABG were truly random, expressing skepticism that external factors (such as insurance status) might influence treatment allocation. These doubts echo broader mistrust in medical research, particularly among Black and Hispanic communities, many of whom noted historic injustices, highlighted in previous literature.<sup>26</sup> Participants emphasized the need for transparency, noting that unless the rationale for randomization was clearly explained, they would remain hesitant to participate in a trial involving major procedures.

**How RECHARGE is responding.** To address concerns about randomization and build trust, RECHARGE incorporates strategies to clarify the trial's structure and purpose. Educational materials created for recruitment (including the trifold brochures and infographics) explicitly state that both PCI and CABG are well-established, evidence-based treatments. These materials explain that the trial is being conducted not because either option is experimental but because experts remain uncertain about which approach yields better outcomes across diverse patient populations like them who have been underrepresented in prior RCTs of PCI vs CABG.

To further support clear and empathetic communication, a community health educator meets with site-based research coordinators to share insights from this qualitative study. These sessions aim to promote patient-centered engagement strategies and prepare staff to address common concerns. For example, recruiters are encouraged to explain that each patient's case is reviewed by a multidisciplinary heart team—including a general cardiologist, interventional cardiologist, and cardiac surgeon—which has determined clinical equipoise. This helps reassure patients that both procedures are medically appropriate and reflect current standard of care.

Importantly, RECHARGE also emphasizes the societal relevance of participation. Recruitment materials clearly explain that most prior trials comparing PCI and CABG have primarily enrolled White men, resulting in gaps in understanding how these treatments affect underrepresented populations. By addressing this disparity directly, RECHARGE invites patients to see their involvement not as passive subjects but as active contributors to more equitable, representative cardiovascular research.

### Conclusions

The present results from the REVASCHOICE study highlight critical opportunities to advance equity in cardiovascular research and care. First, patient-centered outcomes must be prioritized alongside traditional endpoints such as survival, as these factors deeply influence participants' treatment decisions. Second, clear and culturally inclusive education is essential for supporting informed decision making and building trust, particularly at initial points of participant engagement.

Importantly, trust cannot be manufactured through recruitment scripts alone; it must be earned through sustained engagement that considers patients' lived experiences and demystifies research processes such as randomization. Although these insights are vital for designing equitable trials like RECHARGE, they also have broader implications for routine clinical care. Integrating these lessons into both practice and research is essential for addressing disparities and ensuring that cardiovascular care truly reflects the needs of underrepresented populations.

### Limitations

First, although interviews were conducted until thematic saturation was reached, the majority of participants were drawn from a single geographic region, which may limit the generalizability of results to other parts of the United States or international settings. Second, although the interview guide was developed with input from a diverse advisory panel, it is possible that other important perspectives or concerns relevant to potential participants were not fully captured. Third, this study was specifically designed to explore and address barriers to enrollment among women, Black, and Hispanic patients in the United States. However, most participants in this study identified as Hispanic and some as Black, and these findings may not reflect the experiences of other racial, ethnic, or demographic groups eligible for the RECHARGE trial. Additionally, recruitment through academic and community networks may have favored individuals already more engaged with the health care system or with higher baseline health literacy. Finally, although the resulting strategies informed the design of RECHARGE's recruitment approach, they have not yet been formally evaluated for their effectiveness in improving enrollment outcomes.

### Declaration of competing interest

Gregg W. Stone has received speaker honoraria from Medtronic, Amgen, and Boehringer Ingelheim; has served as a consultant to Robocath, Daiichi Sankyo, Vectorious, Miracor, Apollo Therapeutics, Cardiac Success, Occlutech, Millennia Biopharma, Ablative Solutions, Oxitope, Elixir, Impulse Dynamics, Asceneuron, Myochron, Remote Cardiac Enablement, Valfix, Zoll, HeartFlow, Shockwave Medical, Adona Medical, Abbott, HighLife, Elucid Bio, Aria, Alleviant, FBR Medical, Colibri, Bioventrix, and MedHub; and has equity or options from Cardiac Success, Ancora, Cagent, Applied Therapeutics, Biostar family of funds, SpectraWave, Orchestra Biomed, Aria, Valfix, and Xenter. The other authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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### Ethics statement and patient consent

This study was approved by the Columbia University Institutional Review Board, and all patients provided written informed consent before participation.

### Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at [10.1016/j.jscai.2025.104019](https://doi.org/10.1016/j.jscai.2025.104019).

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