Virtual Community Engagement for Retention of Black Men in Clinical Research

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Abstract

Black American men have worse cardiovascular health compared with their White counterparts, yet are highly underrepresented in clinical trials. In 2020, Black men were recruited to participate in Black Impact, a communitybased lifestyle intervention to increase cardiovascular health. Due to the research pause during the Coronavirus Disease (COVID-19) pandemic, a virtual community engagement (VCE) process was co-designed with community stakeholders and evaluated for its effect on retention for the clinical trial. VCE via weekly virtual video conference sessions occurred for 9 weeks as a run-in phase prior to in-person research activities. Data collected during sessions included attendance, anecdotes on acceptability, and topical requests for subsequent weeks. Content analysis was performed on scribe notes from sessions to ascertain themes describing the implementation and participant perceptions of the VCE. Descriptive statistics were used to analyze quantitative data. The VCE provided opportunities to co-create a safe atmosphere in small groups, discuss mental health, foster trust, capitalize on the power of spirituality, and establish a brotherhood. Following the VCE run-in phase, 74 of 100 participants remained engaged for participation in the Black Impact study. The VCE described provides a framework that can be used to retain Black men during study delays or disruptions through fostering engagement and building community among participants and researchers.

Keywords

Black men, clinical trial participation, virtual, community engagement, retention

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Introduction

The Coronavirus Disease 2019 (COVID-19) pandemic has amplified long-standing challenges in recruiting and retaining Black Americans in clinical research. This is concerning considering inequities in diagnosis, hospitalization, and death seen with COVID-19 mirror those of chronic diseases (e.g., diabetes, hypertension, cancer, obesity, and cardiovascular disease [CVD]) among Black Americans (Carnethon et al., 2017). CVD, which includes hypertension, congestive heart disease, stroke, and heart failure, persists as one of the leading causes of death in America. Disparities in CVD morbidity and mortality that are influenced by social determinant of health factors disproportionately affect Black Americans who are more than twice as likely to die of CVD compared with their ¹The Ohio State University College of Nursing, Columbus, OH, USA ²The Ohio State University Comprehensive Cancer Center, Columbus, OH, USA

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White American counterparts (Tsao et al., 2022). When examining sex-specific disparities, Black American men (henceforth referred to as Black men) have the highest rates of hypertension-related CVD, ischemic heart disease, heart failure, and cerebrovascular disease (Rethy et al., 2020). Namely, Black men are 32% more likely to die from CVD than their White American counterparts (Carnethon et al., 2017; Virani et al., 2021), and the pandemic may exacerbate related premature death among Black men by 3.3 years (Arias et al., 2021). Yet, Black Americans represent only 16% of participants in trials leading to new drug approvals and only 2.5% of participants in cardiovascular clinical trials (Ortega et al., 2019; Turner et al., 2022). This highlights an opportunity to operationalize community-based participatory research (CBPR) to improve cardiovascular health and decrease chronic disease prevalence among Black men (Elgazzar et al., 2020).

A growing body of literature has identified CBPR, which engages stakeholders as research partners throughout the conduct of research, as an exemplary model for engaging underrepresented groups in research (Israel et al., 2010; Minkler & Wallerstein, 2011). Yet, there is a paucity of studies employing CBPR principles to engage Black American populations in prevention or treatment of chronic diseases. Before the COVID-19 pandemic, general barriers such as employment, transportation, burdensome surveys, child care, and personal constraints may have hindered prospective participants from participating in clinical trials. Some researchers have also failed to invite Black men to join clinical trials (Brewer et al., 2021; Clark et al., 2019). Black Americans were overrepresented in the low-wage essential workforce, which is typically associated with the absence of paid time-off and inflexible schedules (Gould & Wilson, 2020). All of these components, coupled with medical mistrust and past experiences of racism and discrimination in health care and clinical trial settings, may have contributed to the lack of Black participation in clinical trials (Gray, Joseph, et al., 2020; Gray, Nolan, Bignall, et al., 2021; Gray, Nolan, Gregory, & Joseph, 2021; Nawaz et al., 2020; Watson, Turner, & Hines, 2020).

The COVID-19 pandemic has magnified the challenge of clinical trial recruitment and retention of Black men. Although the aforementioned barriers are ever-present, many barriers have been exacerbated since 2020. It is no surprise that mandates against physical gathering and nonessential travel, which have severely limited mobility and engagement throughout society, would further hinder Black male participation in clinical trials. For example, physical-distancing mandates instituted during the height of the COVID-19 pandemic necessitated the use of alternative engagement methods in clinical trials (e.g., virtual platforms) to promote clinical trial reach and engagement of Black men (U. S. Food & Drug Administration, 2020). However, virtual participation opportunities among Black men may have also been hindered in comparison with their White counterparts due to a lack of access to computer devices and Wireless Fidelity (Wi-Fi) networks (Fryer et al., 2016). Therefore, it was necessary to develop alternative approaches to safely engage with this population.

A CBPR, lifestyle intervention program called "Black Impact" (BI) demonstrated that a research team can identify and address known barriers to Black men's clinical trial participation to encourage both participant recruitment and retention. Clinician-scientists at the Ohio State University, their community partners at the African American Male Wellness Agency, and community members co-designed the clinical trial (Clinical trial.gov identifier: NCT04787978) to study the intervention's effect on attainment of ideal cardiovascular health, as defined by the American Heart Association's Life's Simple 7 metrics, among Black men in locale-based teams (Joseph et al., 2022; Lloyd-Jones et al., 2020). The co-design process applying the PETAL framework, fully described elsewhere, ensured that community members and partners were included in the formulation of programming topics and strategies used in the intervention (Brooks et al., 2017; Joseph et al., 2022). The CBPR framework afforded researchers the opportunity to reckon with medical mistrust and address the barriers to participation by intentionally engaging community members and stakeholders throughout the design, implementation, and dissemination process of a study (Cooper, 2021; Gray et al., 2020, 2021). However, the intervention phase, originally designed as in-person team-based education and physical activity, was halted 1 month prior to its launch when COVID-19 pandemic shelter-in-place order was issued. Unfortunately, there were no existing frameworks to reference for retaining participants during a pause to research operations and social gathering. Therefore, the investigators and community partners (study team) devised a flexible retention plan using CBPR principles that withstood federal-, state-, and university-level changes to social gathering restrictions. Here, we describe the development of this virtual community engagement (VCE) process and its impact on clinical trial participation and engagement on the allowance for safe social gathering in research operations.

Method

The BI study, including amendments described below, was approved by the Ohio State University Institutional Review Board in July 2020 (No. 2019H0302). All 100 participants (Black men with less-than-ideal cardiovascular health, living in a Midwestern Ohio metropolitan area, with no health care provider-indicated contraindications to participation) provided informed consent for participation (Joseph et al., 2022). In response to the pause of all in-person research activities at the Ohio State University in March 2020, the VCE was prospectively designed as a 9-week "run-in" phase to engage and retain the men in the BI study. Of note, participants expressed their interest in remaining involved while waiting for approval to initiate the in-person intervention study and suggested a virtual option. Thus, our study team members (along with men who had consented to participation in the Black Impact study) co-created VCE through weekly virtual video-conferencing meetings with study participants. Attention was given to ensure that men could access the virtual platform without issue by connecting five men without stable internet access to the federally funded Emergency Broadband Benefit (providing a reduced internet rate and access to hotspots that were confidentially placed throughout their communities). In addition, all men received information regarding alternative devices (e.g., using personal or borrowed smartphones, company-issued laptops, reserving space and computers at local libraries, and/or checking-out iPads from the study team) that could be used. Furthermore, the study team provided all men with written instructions and a live online tutorial to support any participant who may have been unfamiliar with virtual platforms (i.e., Zoom).

Given the unprecedented times of the pandemic, both the study team and participants collectively decided that VCE was needed to not only dispel myths and validate truths about the COVID-19 pandemic but also to keep enrolled participants engaged for the initiation of the Black Impact study. Through the iterative co-design process, the latter weeks of the VCE evolved into a holistic educational dialogue that incorporated the needs and interests of the participants. The iterative co-design process involved (a) the study team collecting session attendance, scribing notes on the acceptability of each session (e.g., What did you like/dislike about this week's session? Do you have recommendations for future topics?), and scribing notes that captured the organic conversations that derived from participant interests; (b) two independent coders (T.S.N. & A.M.) performing inductive content analysis on scribed notes using open coding practices and iterative sessions to reduce codes to themes describing session implementation and participant responses to VCE with consensus; and (c) querying participants at weekly sessions to validate themes (Creswell, 2002; Eaton, Stritzke, & Ohan, 2019). Of note, descriptive statistics were used to analyze quantitative data. The resultant 9-week VCE curriculum is presented in Table 1.

Following approval of amendments to the institutional review board (IRB) protocol to allow for virtual engagement and an extension of time, the study team worked with study participants to secure a mutual meeting day and time throughout the week. The study team members then instituted a communication system with the men to encourage their participation in the virtual sessions. The men received weekly emails with minutes from the previous meeting and reminders of the upcoming meetings through text messages, phone calls, and emails from BI's study team members. The reminder communication included the video teleconferencing uniform resource locator (URL) link, time, discussion topic, and guest speakers.

Each session followed a similar format. The sessions were 1 hr in length. The larger group meetings opened to all study participants allowed for meaningful discussion around the topics presented each week (see Table 1). Each topic was facilitated by an expert in the respective field who was identified from the study team's networks. Each facilitator was directed to create session content that provided lay information that also prompted audience participation. During Week 5, participants requested to have separate meetings in their previously designated BI teams. The six self-selected BI team captains began co-facilitating a weekly 1-hr small group Zoom call with a lead investigator, BI study team member, and fellow team members. These smaller sessions allowed in-depth engagement and discussion of the weekly topics in a smaller setting. Byproducts of the captain-led, small group sessions also included fellowship around personal topics such as challenges at work, new business ventures, and the impact of COVID-19 and racism in their communities. Thus, by Week 5, participants had the opportunity to receive up to 2 hr of engagement (1 hr of team-based BI sessions and 1 hr in the large group). In addition, to increase inclusiveness around program design, the study participants were invited during three of the nine large group sessions to facilitate a portion of the sessions. Thus, the curriculum and its implementation were informed and led by those who had consented to participate in the postponed in-person BI study. After completing the VCE, the study team and participants reflected on the prospective co-design process via additional inductive content analysis of scribed notes. Findings are presented in the following section.

The number of participants in the larger sessions ranged from 20 to 47, while the small group sessions ranged from five to 12 men in attendance. The men attending these sessions voiced a sense of ownership in the program due to their ability to select discussion topics. As described in Table 1, the sessions included the following topics: COVID-19, mental health, conflict resolution, financial literacy, health and nutrition, and homeownership. The participants noted that the weekly sessions provided a platform to discuss personal information, breaking traditional communication boundaries among men. Moreover, the VCE provided the men with opportunities to co-create virtual small group sessions,

Week	Торіс	Speaker	Content
I	COVID-19	Three lead clinician–scientists	 What is COVID-19 and how is the virus transmitted Ways to reduce exposure Updates on state and federal COVID-19 ordinances
2	Mental Health	Two clinical psychologists	 Common themes—mindfulness, self-compassion, isolation, and when to seek professional help Practical solutions were provided to redirect negative thoughts and behaviors—chair yoga, creating daily rituals/routines, self-massage, box breathing, and hand tracing
3	Mental Health	Social worker	 Open and candid discussions on impact of the pandemic Identifying and coping with stress
4	Financial Literacy and Budgeting	Local financial blogger	 Debt-reduction, budgeting and overview of Dave Ramsey's 7 Baby Steps Discussions on successes and challenges with personal finances
5	Mental Health and Conflict Resolution	Licensed professional counselor	 Collective challenges—relationship conflict, unemployment, isolation, depression, anxiety, insomnia, and routine disruption
6	Health and Nutrition	Licensed chef	 A complete cooking demo preparation on wild salmon dish with two plant-based sides Tips on purchasing fresh produce Healthy alternatives to meat and how to read labels
7	Health and Spirituality	Pastor	• Spiritual mindfulness and ways in which spirituality can help navigate challenging times
8	COVID-19	Three lead clinician–scientists	Credible local and national resources
9	Financial Literacy and Homebuying	Representatives from banking institution and state home buying program	 Budgeting, savings, investment, and retirement preparation Housing—mortgage, lending services, affordable housing

Table I. Weekly Virtual Series Curriculum.

Note. Each session began with updates on local, state, and federal updates on COVID-19 recommendations and ended with a question and answer session on COVID-19.

discuss mental health, foster trust, capitalize on the power of spirituality, and establish a brotherhood (see Figure 1).

Co-Creation of Small Group Virtual Sessions

The participants transformed the communication outlets that were initially planned, by creating additional small group sessions, providing them VCE to support and strengthen their brotherhood. Through texts, calls, emails, and private Facebook groups, the men encouraged each other to attend both weekly sessions; provided updates on COVID-19; shared healthy cooking recipes and exercise tips; and sought help on personal and professional issues such as managing the hardships of being a Black man dealing with the personal and societal impacts of systemic racism. During these weekly small group sessions, participants also conveyed the benefits of the pandemic, such as spending more time with loved ones, connecting with old friends, discovering new hobbies, time for selfreflection, and rest.

Mental Health

Discussions around mental health were amplified during these sessions. Many men shared feelings of depression, isolation, and yearning for in-person interactions with family and friends lost due to the pandemic. There was high anticipation for the weekly video-conferencing among the men, and for some, this was the only meaningful engagement they had with another person due to COVID-19 stay-at-home orders. The calls increased trust and cultivated a brotherhood within the groups. Men resonated with each other's life stories, which allowed them to openly share concerns and fears about COVID-19, unemployment, isolation, health history, and relationship conflicts.

Trust

Many participants stated that weekly meetings created a trusted space where "brothers" could share their life



Figure 1. Virtual Community Engagement Note. This figure is a depiction of the components of virtual community engagement that led to retention of 74 of 100 Black men who consented to take part in the parent study, Bl program. BI = Black Impact.

experiences without judgment. Many also felt overwhelmed by conflicting messages about the virus from various news channels and governing bodies. Of note, the men expressed interest in racially concordant facilitators for each session; however, they did not express a preference for sex concordance. During the session, the men stated that "having Black doctors" who they have come to know and trust (facilitated by initial affiliation with a trusted community partner) empowered them to make informed decisions for themselves and their families.

Spirituality

There were numerous testimonies on the impact of spirituality. The men expressed how COVID-19 turned their homes into a multifunctional space for work, child care, school, exercise, and a place of worship that at times could be isolating. The isolation of quarantining disconnected many from their weekly church services and inperson gatherings with family and friends. Many men said that they remained connected with their church community through weekly virtual worship services and bible study sessions. "Leaning on faith" gave the men the needed solace and hope. An Ohio-based pastor spoke on spiritual mindfulness and ways in which spirituality can help navigate challenging times. The session on spirituality was the highest attended, with 47 participants.

Brotherhood

The weekly virtual connection chats restored the men's faith and strengthened their relationships with those around them. The weekly VCE that began in March 2020

cultivated a brotherhood among the men throughout the study. The men credited their brotherhood for creating an environment of accountability that motivated and strengthened their commitment to starting the in-person intervention. Although the men were aware of the program's value, many shared that they felt a sense of obligation to attend the sessions because "I didn't want to let my brothers down." The men's dedication to the program transformed from wanting to improve their health to the collective health of their "brothers" and the larger community. This brotherhood helped retain 74 of the 100 men at the start of the in-person, parent study intervention in July 2020. Those lost to follow-up had alterations in living situations, employment, or other issues outside of their control.

Discussion

Due to the unprecedented and ever-changing nature of the COVID-19 pandemic, members of the study team cocreated and implemented weekly VCE sessions as an avenue to retain previously recruited Black men in the BI study. Utilizing CBPR principles allowed for the flexibility and adaptability needed to move forward with work in a community setting as many other research teams awaited directives from their respective institutions on how to conduct community-based research and engagement safely (Brooks et al., 2017). Through stakeholderengaged processes, the study team members interacted with up to 47 participants during our VCE process that featured weekly group discussions on topics relevant to their needs. Study team members involved experts from their networks (e.g., multiple universities, local and state community partners) and study participants in facilitating weekly meetings, leading to the retention of 74 of the 100 Black men initially recruited for the parent study during a pandemic. Importantly, these Black men were sociodemographically diverse with a mean age of 52, primarily insured (74%) and employed (84%), and varied income (Joseph et al., 2022). These results demonstrate that Black men can successfully be retained in communitybased interventions through VCE.

Literature on conducting VCE in CBPR studies, particularly during a global pandemic, is sparse. A review of the literature revealed that most studies addressing the health, wellness, and the reduction of preventable illnesses among Black men mimic the operations of the Black Barbershop Outreach Program (BBHOP) (Releford et al., 2010). Since the inception of BBHOP in 2006, 30,000 Black men have been screened for diabetes and high blood pressure through collaborative efforts with grassroots organizations and an academic health system. Although there are similarities to the BI study's objectives and partnerships to improve cardiovascular health,

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BI is unique in that the study team members had to uncover how to meaningfully engage participants during a pandemic while physically unable to move forward with the intended in-person intervention phase.

Although historical and present-day barriers to clinical trial participation exist, several facilitators supported retention of Black men using a VCE process during a pause in research operations for participation in our BI study. First, using of a multimodal intervention model allowed collaborators from different sectors to effectively leverage resources and expertise to improve the health of Black men. This involved academic, community, and government partnerships connecting to attain a shared goal of engaging Black men in conversations that were seen as acceptable and valuable to them (Gray, Nolan, Bignall, et al., 2021; Joseph et al., 2021). In this case, multiple community stakeholders supported the 9-week VCE sessions by providing their expertise on critical issues that affected the health of Black men, such as COVID-19, mental health, finance, nutrition, and spirituality. Second, culturally tailored messaging was equally important and valuable to disseminating material (Niranjan et al., 2019). Black men's reception of information significantly affects their application of that information. Overcoming mistrust by the provision of a credible messenger was imperative to the men's willingness to embrace the information. Third, racial concordance of a researcher with Black research participants may be important, especially during recruitment but also for retention (Kahn et al., 2021). Although racial concordance assists in initiating connections between researchers and participants, there remains a need for research staff to build concordance with participants' goals and values while tackling the needs of the community (Fryer et al., 2016). Therefore, retention was likely made possible by the study team's intentionality around ensuring processes were sensitive and inclusive of ideas shared by its team members and the BI study participants.

The 9-week VCE process not only served as a significant resource to sustain the momentum between the time that the men were recruited and enrolled and the initiation of the in-person BI study but also provided the participants with an outlet for social interaction during the COVID-19 pandemic. Once trust was established among participants, there was a flow of meaningful engagement and development of relationships. The continuous adjustments in response to engagement with all stakeholders were noted to elevate participants' commitments to remaining in the BI study. To our knowledge, this is the first description of a virtual "run-in" phase of a CBPR study among Black men amid a pandemic. The brotherhood that was developed during the VCE carried over into the 24-week intervention phase of the trial, laying the foundation for needed self-care and healing.

Limitations

This study of VCE features several limitations. First, the VCE presented was not originally intended to be a focal point of research. Therefore, an iterative process of engagement without formal metrics such as sociodemographic information or consistent attendance was collected inscribed notes. Therefore, we discussed sociodemographic information derived from the 74 men who remained engaged to begin the in-person intervention phase in July 2020 and presented aggregate data from sessions with scribed notes on attendance. Second, the use of primarily qualitative methods with the subset of Black men attending each session may lend itself to the creation of biases. Thus, by definition, we cannot generalize conclusions to the larger group of consented study participants nor the population at large. Finally, although the research team provided the men with many resources through which to access the internet needed to participate, it is possible that this may have been a barrier to participation for some participants.

Conclusion

Black male participation and retention in research are imperative to advancing health equity. Pivoting to VCE can improve Black men's participation in clinical trials during disruptions or delays in CBPR. An academiccommunity-government partnership illustrated how using principles of CBPR can lead to engagement and retention of Black men. A multimethod approach allows researchers and participants to function in a co-developed reciprocal partnership with ongoing programmatic development. During a pandemic, BI study team members recruited 100 Black men and, through development and implementation of a prospectively-created VCE, retained 74 men to participate in the BI intervention study. Although the pause in research operations caused by the pandemic necessitated the development of VCE for retention, future studies should formally evaluate best practices and the effect of VCE as a component of research retention plans. Outcomes of such research may improve clinical trial implementation and retention of Black men in clinical trials.

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