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A multi-perspective study assessing Black and African American participation barriers in prostate cancer clinical trials

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ABSTRACT

Aims: This study aimed to partner with patients, advocates, and physicians to better understand the barriers that exist for Black and African Americans to enroll in prostate cancer (PCa) clinical trials.

Patients & Methods: Through moderated discussions with patients, advocates, and physicians, we identified potential opportunities to increase the enrollment of underrepresented patients in PCa clinical trials.

Results: We identified key barriers to Black and African American enrollment in PCa clinical trials that were shared by all groups but also identified group-specific barriers. We developed recommendations based on key themes that have the potential to increase the enrollment of Black and African Americans in PCa clinical trials.

Conclusions: While racial diversity in PCa clinical trials remains an unsolved problem, there are significant opportunities to better address this unmet need. Through a multi-perspective approach to identify key barriers that limit Black and African American enrollment in PCa clinical trials, we developed recommendations for both sponsors and clinical trial sites to increase diverse patient enrollment in PCa clinical trials, with a focus on employing practical strategies.

PLAIN LANGUAGE SUMMARY

This is a study to investigate why there are low numbers of Black and African Americans participating in prostate cancer clinical research. Clinical trials help us understand if new cancer medications are better at treating cancer than medications that are currently available, and additionally what side effects they may cause. Medications can have different effects in different groups of patients; therefore, it is important that clinical trials include all different kinds of patients, especially patients from different racial and ethnic groups. However, prostate cancer clinical trials do not enroll enough Black and African Americans even though the rate of prostate cancer is higher in Black and African Americans than other groups of Americans. In this study, we asked physicians, patient advocates, and patients why they believe there are low rates of Black and African Americans in prostate cancer clinical trials. We worked with all three groups to identify potential ways to increase clinical trial participation by Black and African Americans.

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1. Introduction

In 2025, there will be approximately 313,780 new cases and 35,770 deaths from prostate cancer (PCa) in the United States [1]. PCa disproportionately affects non-Hispanic Black people at a higher rate (189 per 100,000) than all other races, including non-Hispanic Whites (115 per 100,000) and Hispanics (88 per 100,000) [2]. Non-Hispanic Black people also have a higher death rate (37 per 100,000) than non-Hispanic Whites (18 per 100,000) and Hispanics (15 per 100,000) [2]. Furthermore, National Institutes of Health Surveillance Epidemiology and End Results (SEER) data showed that Black and African Americans had an earlier age at diagnosis (mean 69.1 vs 71.1 years) and shorter survival period (mean 44.4 vs 48.4 months) compared to White patients with PCa [3].

Despite higher PCa incidence and mortality rates, Black and African Americans are historically underrepresented in PCa clinical trials. A recent analysis of 51 PCa treatment clinical trials (n = 35,014) found that only 6.7% of participants identified as Black or African American [3]. Similar results were found across four PCa prevention clinical trials (n = 62,424; 8.5% Black and African American identifying) and across 4 PCa screening clinical trials (n = 746,564; 0.5% Black and African American identifying) [4].

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Article highlights

- This study, by hosting moderated discussions with patients, advocates, and physicians, identified key barriers for each group that contribute to low Black and African American enrollment in prostate cancer (PCa) clinical trials.
- Key barriers in the patient group included systemic barriers such as not being equally offered clinical trial opportunities, ineffective clinical trial outreach strategies by institutions and sponsors, and difficulty interpreting clinical trial language and inclusion/exclusion criteria.
- Key barriers in the advocate group included lack of community funding for awareness and education initiatives, insufficient support for PCa awareness efforts from local and state government officials, and research outreach efforts that rely on patients engaging study sites first, rather than bringing research to diverse patients.
- Key barriers in the physician group included poor trial execution strategies toward diversity, competitive enrollment not allowing time to employ diverse patient outreach strategies, and high rates of uninsured and underinsured patients, making pre-trial screening and testing difficult to schedule and complete.
- Based on key barriers identified across all three groups, we developed recommendations to potentially increase the enrollment of Black and African Americans in PCa clinical trials.

Furthermore, an analysis of landmark Castration-Resistant PCa trials found that only 11–31 Black and African American patients received an investigational agent per trial, highlighting the difficulty in performing efficacy subgroup analyses in this population [5]. The source of these disparities remains under-investigated, which underscores the need for focused study.

This study aims to better understand the barriers that exist for Black and African American patients to participate in prostate cancer clinical trials. Using a multi-perspective approach, we hosted three moderated discussions with participants that represented physicians, Black and African American patients, and patient advocates. The multiple perspectives represented by the moderated discussions led to specific ideas and strategies for institutions and pharmaceutical companies to consider implementing for future clinical trials.

2. Patients & methods

In partnership with the Center for Information and Study on Clinical Research Participation Inc (CISCRP), a nonprofit 501(c)(3) organization, we conducted three moderated discussions between May and September 2023. Each advisory board consisted of a unique stakeholder group: (1) physicians that treat PCa; (2) patient advocates involved with PCa advocacy; (3) Black and African American patients with PCa (Table 1). All participants were screened for relevance to the discussion, and each provided both written and verbal consent to participate (Figure 1).

This project was deemed exempt by an institutional review board (WCG IRB) because the research only includes interactions involving educational tests, survey procedures, interview procedures, or observations of public behavior; and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects. Regardless, verbal and written informed consent was obtained from each participant. All patient and advocate participants were screened for relevant experience in the subject matter by CISCRP. Participants were required to have access to a computer and a web camera. To reduce participation barriers, all participants were compensated for their time.

Each discussion was led by one moderator and conducted as a 2-h virtual meeting (to reduce participation barriers) aiming to better understand enrollment obstacles and identify strategies to increase diverse enrollment in prostate cancer clinical trials. As an additional layer of confidentiality for participants, these discussions were not recorded, however, a designated note taker was present for all discussions. Discussions were conducted using semi-structured interview guides specifically designed for each group, however, moderators had flexibility to diverge from the moderator guide when participants introduced relevant topics. Following each moderated discussion, CISCRP analyzed collected notes and created summaries capturing key takeaways. A thematic analysis approach was used to identify patterns and themes to describe data collected across all moderated discussions (physician, patient, advocate). CISCRP's knowledge and previous experience within the DEI and patient engagement landscape was leveraged to identify key themes.

Table 1. Participant demographics.

A) Physicians	
Specialty – no. (%)	
Medical oncology	5 (71)
Radiation oncology	1 (14)
Urology	1 (14)
Practice Setting – no. (%)	
Academic	5 (71)
Community	1 (14)
Mixed	1 (14)
B) Patient advocates	
Previous prostate cancer diagnosis – no (%)	
Yes	6 (86)
No	1 (14)
Years of advocacy – no. (%)	
5+ years	1 (14)
10+ years	3 (43)
25+ years	3 (43)
C) Patients	
Median age (range) – yr	65 (60–73)
Median age at diagnosis – yr	59 (41–70)
Clinical trial experience – no. (%)	
Yes	2 (29)
No	5 (71)
Advocacy experience – no. (%)	
Yes	4 (57)
No	3 (43)
Education – no. (%)	
High School	1 (14)
Technical School	1 (14)
Bachelor's degree	4 (57)
Law degree	1 (14)

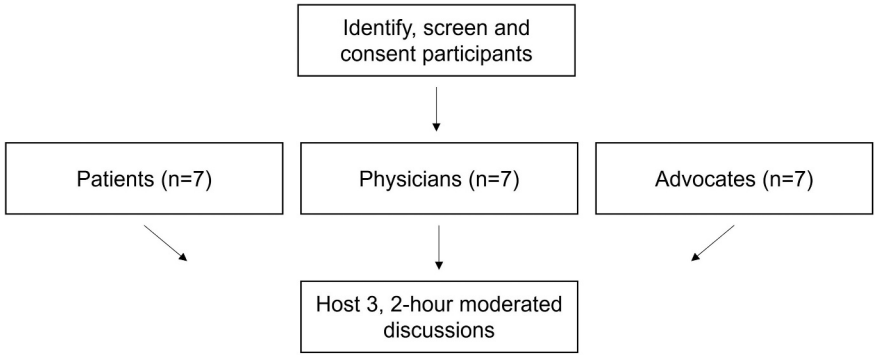

Figure 1. Participant identification process.

3. Results

3.1. Group demographics

The physician group ($n = 7$) included five medical oncologists, one radiation oncologist, and one urologist. Physicians represented six geographically distinct areas including Atlanta GA, Los Angeles CA, New York NY, Philadelphia PA, Washington DC, and Fort Myers FL (Table 1). Five physicians practiced in an academic setting, one practiced in a community setting, and one practiced in a mixed setting.

The patient advocate group ($n = 7$) included participants from the mid-Atlantic, northeast, and northwest United States. Once participant now lives in Europe. Six patient advocates had a current or previous prostate cancer diagnosis and one did not. Advocates had a range of experience in both years and type of advocacy (5–9 years; $n = 1$, 10–24 years, $n = 3$, 25+ years, $n = 3$; patient, legal, governmental).

The Black and African American patient group (self-identified, $n = 7$) included patients from the northeast, southeast, and south-central United States. The median patient age was 65 yr (60–73), while the median age at diagnosis was 59 yr (41–70). Only two patients had prior or current clinical trial experience. Four patients had advocacy experience, while three patients did not. This group included a range of education levels (High School; $n = 1$, Technical school; $n = 1$, Bachelor's degree; $n = 4$, Law degree; $n = 1$).

3.2. Key learnings

We identified key themes that were shared among participants that help explain the health inequities and disparities that Black and African Americans face in clinical research (Table 2). The importance of certain themes varied among the stakeholder groups.

Table 2. Key barriers identified in each group.

Physicians	Patient advocates	Patients
Poor trial execution strategies toward diversity	Lack of community funding for awareness and education initiatives	Systemic barriers, such as not being equally offered clinical trial opportunities
Competitive enrollment does not allow time to employ diverse patient outreach strategies	Insufficient support for PCa awareness efforts from local and state government officials	Ineffective clinical trial outreach strategies by institutions and sponsors
High rates of uninsured and underinsured patients makes pre-trial screening and testing difficult to schedule and complete	Research outreach efforts rely on patients engaging study sites first, rather than bringing research to diverse patients	Difficult to interpret clinical trial language and inclusion/exclusion criteria

3.2.1. Systemic and socio-economic barriers

Participants from all three stakeholder groups highlighted that the US health care system, at both the physician and patient level, is difficult to navigate. High rates of uninsured and underinsured Black and African Americans can make pre-trial screening and testing difficult to schedule and complete. Travel distance for the patient and trial site location, cost of traveling, lack of patient time, inability to take time away from work or family for screening, treatment, and follow-up visits were other systemic and socio-economic barriers that were identified uniformly.

The requirement for self-advocacy was a common theme among patient discussions, which may reflect prior personal experiences or mistreatment from health care workers [6]. For example, one patient shared how they had to persuade their physician, after an abnormal prostate-specific antigen (PSA) test, to order additional testing instead of a "watch and wait" approach. Additionally, several patient participants reported that they did not maintain annual visits with their primary care physician, but only sought medical attention when they experienced a specific medical issue, such as pain. Both patients and advocates stressed the need for clearer PSA screening guidelines for Black and African Americans by the US Preventative Services Task Force.

3.2.2. Lack of trust in the US health care system

First, both patients and advocates were skeptical of clinical research because they did not want to feel like "guinea pigs." Some participants felt that the pharmaceutical industry has yet to acknowledge and repair past injustices, such as the Tuskegee experiment [7]. While the Tuskegee experiment was conducted by the United States Public Health Service (USPHS), patients still associated the study with the medical and pharmaceutical industries. Patients described sometimes feeling inequity and racism

in clinical settings but also vocalized that representation is important. For instance, one patient participant recalled feeling isolated after his diagnosis as a young Black male, as there were no resources or materials to which he could relate. Patient participants also shared that Black and African American providers and site staff made them feel represented, more comfortable, and improved trust.

Second, some patients were unclear how an individual patient may benefit from clinical trials. This coincided with the feeling of not wanting to be randomized to the "placebo group" of a clinical trial, despite the reality that placebo arms are infrequent and control arms usually represent the current standard of care treatment. Patients also felt that they were not properly recognized for their contributions when participating in a clinical trial. This may be exacerbated by survey data suggesting that while most patients want to see the results of the clinical research they participate in, only about one-third of patients receive the results, with over half of patients not even having an opportunity to request the results [8].

3.2.3. Lack of education and community awareness

Black and African American patients felt that lack of awareness and education about clinical trials as a treatment option contributes to underrepresentation in clinical trials. Patients also shared that they do not know how to identify clinical trials for which they may be candidates. Both patients and advocates voiced that clinical trial outreach strategies targeting diverse patients are ineffective, and usually rely on patients engaging study sites first, instead of meeting patients where they are and bringing clinical research to diverse patients.

While advocates shared varying community outreach and education efforts, these efforts often fell short of their goals and had to be shut down due to a lack of funding. Advocates also felt that prostate cancer awareness efforts lacked support from local and state government officials when trying to pass new initiatives or collaborate with pharmaceutical companies.

3.2.4. Poor trial execution strategies toward diversity

Trial execution strategies were raised as a barrier to diverse clinical trial enrollment at multiple levels. While there has been an increased focus on enrolling diverse patient populations that are reflective of disease epidemiology, competitive enrollment does not allow time to employ diverse patient outreach strategies. Additionally, as budgets generally do not reimburse or mandate diverse inclusion, continued progress and executionremain difficult.

PCa clinical trial site selection was also raised as an obstacle to enrolling diverse patients. Many PCa clinical trials are held at academic centers, rather than local community clinics or hospitals where more diverse patients are being treated. As previously mentioned, the burden of traveling to academic sites poses a significant challenge for some to participate in a clinical trial. Additionally, as some patients are initially treated at local clinics and hospitals upon diagnosis, they may no longer be eligible for certain clinical trials, as compared to those who are originally cared for at academic centers. Lower levels of disease awareness and education around PSA screening can also lead to patients arriving at clinical trial sites with more advanced disease, rendering them ineligible for earlier-stage disease trials, as well as negatively impacting their prognosis.

Physicians felt that oncology clinical trial designs are prohibitive to the participation of underrepresented Black and African American patients. Inclusion and exclusion criteria can unintentionally exclude patient groups, especially Black and African American patients. This sentiment was echoed by patients who felt that when they do seek out clinical trial opportunities, they are often frustrated by the seemingly confusing and narrow inclusion and exclusion criteria, which makes them feel excluded from the trial before even speaking to a physician.

Initiating clinical trial discussions may be another significant barrier; patients felt that physicians do not equally discuss research participation opportunities among all racial and ethnic groups due to provider bias. A similar sentiment was raised by physicians, in that non-Black or African American physicians may feel like an outsider when discussing trials with this group of patients. With only a limited amount of time to spend with patients, physician investigators may make assumptions about which patients may or may not be interested in a clinical trial, and ultimately choose to forgo spending the additional extra time it would take to discuss a clinical trial with certain patients.

3.2.5. Strategies to promote prostate clinical trial diversity

In addition to identifying key barriers to diverse patient enrollment into PCa clinical trials, we also developed strategies and recommendations to improve underrepresented patient enrollment.

(1) When selecting clinical trial sites, study sponsors may consider selecting sites, such as rural clinics or community hospitals, that can have a higher percentage of underrepresented patients. Additionally, sponsors may consider allowing patients, when possible, to utilize local clinics for active follow-up including imaging, blood chemistry, and urinalysis. This approach may allow more underserved patients to enroll in clinical trials by reducing travel time, time off work, and childcare support. Importantly, telehealth visits should strategically be allowed, when possible, to reduce the number of scheduled visits to make clinical trial participation easier for patients [9].
(2) To incentivize clinical trial sites for enrollment of underrepresented patients, provide additional sponsor funding and support for sites to develop targeted outreach and enrollment strategies.
(3) Increase diversity in clinical trial steering committee members and study investigators. Data suggest that despite interest in clinical research being similar among Black and African American and White physicians, minority physicians, and specifically Black and African American physicians, participate in fewer clinical trials, partly due to infrastructure and support limitations [10,11]. Additionally, taking the *New England Journal of Medicine* as an example, Black authorship

has increased only 0.5% since the year 2000 [11,12]. Increasing diversity in clinical trial team representation may increase trust among the targeted underserved population. For instance, when presented with prostate cancer online videos, Black and African American adults had significantly more trust in information when it was presented by a Black or African American speaker [13].

(4) Re-evaluate clinical trial inclusion and exclusion criteria to mitigate medically unnecessary Black and African American exclusion from enrollment. When developing clinical trials, whenever possible, consider adjusting inclusion and exclusion criteria, especially for therapeutic agents with previously established safety profiles. An analysis of 113 cardiovascular clinical trials found that only one justified the exclusion criteria that the investigators applied to the trial [14]. Such adjustment of inclusion and exclusion criteria may also increase the generalizability of clinical trial results across more diverse patient groups.

(5) To simplify clinical trial information for patients, develop patient-level enrollment materials. Underrepresented patients may be more willing to proactively engage clinical trial sites when inclusion and exclusion criteria are presented in easy-to-understand language that makes them feel like they can participate in the study.

(6) Bring clinical trials to patients. Patients felt that sponsors and clinical trial staff should engage with Black and African Americans about clinical trials at non-conventional locations such as churches, historically Black colleges and universities (HBCUs), fraternities, and similar community settings. For instance, it was suggested that clinical trial representatives or investigators can collaborate with local churches to host educational health fairs, where there is an opportunity to raise awareness about clinical research opportunities.

4. Discussion

To better understand the barriers that Black and African Americans face when enrolling in PCa clinical trials, we hosted three advisory boards with key stakeholders including patients, advocates, and physicians. We identified key existing barriers to enrolling diverse patients in PCa clinical trials. Certain themes, such as systemic and socio-economic barriers and trial execution strategies, were shared among all three groups, however group-specific themes did emerge. For instance, patients tended to focus more on issues around trust or understanding of clinical trials, advocates focused more on the lack of education and community funding, and physicians focused more on clinical trial design, execution, and working with industry sponsors.

Inclusion and exclusion criteria were raised as a barrier to enrollment by both physicians and patients. For example, a study evaluating pancreatic cancer clinical trials found that traditional eligibility criteria disproportionally excluded more Black and African Americans based on prior medical conditions [15]. A retrospective study of 401 interventional PCa clinical trials found that 47.9% used laboratory value criteria (serum creatinine and absolute neutrophil count) that disproportionately excluded Black and African Americans and that altering these pre-requisite laboratory value requirements could increase eligibility among this group [16].

Patients and advocates raised their concerns over perceived insufficient screening guidelines for Black and African Americans. Recently, the Prostate Cancer Foundation provided new screening guidelines for Black and African Americans that recommends earlier PSA screening starting between ages 40 and 45, and as early as 40 for those at higher risk due to a strong family history or known carriers of high-risk genetic variants [17]. The American Urologic Association (AUA) similarly recommends Black and African Americans undergo PSA screening starting at the age of 40 [18].

In 2022, the Federal Drug Administration (FDA) released a draft guidance for industry titled "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials" [19]. This draft guidance details how and when diversity plans should be submitted to the FDA for medical products and includes directions on specific information that the diversity plan should contain.

An interesting theme that emerged from discussions with patients and advocates was the importance of female caregivers. It was suggested that sponsors and clinical trial sites can better reach diverse patients for clinical trials by engaging with female caregivers such as wives or daughters, as they were considered highly influential in treatment decision-making, and were considered shared-decision makers. This includes developing specific and targeted outreach to female caregivers. Patients and advocates suggested partnering with sororities to reach potential female caregivers to disseminate prostate cancer information, host educational sessions, and educate about ongoing clinical research. Another theme that emerged was the idea of increasing community presence, where it was suggested that sponsors and clinical trial sites can build trust by engaging with communities early on, even before clinical trials are initiated. Patients and advocates felt that sponsors often fail to develop a community presence, and often only engage the community when they are specifically looking to meet clinical trial enrollment goals.

Efforts are ongoing among institutions to increase the number of diverse patients in clinical trials and increase overall health equity. At Mount Sinai Hospital, the Robert F. Smith Mobile Prostate Cancer Screening Unit was launched in 2022, focusing on educating Black men about the prostate while providing prostate cancer screening and referral for treatment when needed. In fact, for the first 8 months of operation, the team saw more than 1,800 patients, and importantly, 69% of those seen were Black men. The Ralph Lauren Center for Cancer Prevention (RLCCP), part of the Georgetown Lombardi Comprehensive Cancer Center, aims to achieve cancer care equity through identification, testing, and screening, to increase the proportion of Black and African patients that have access to screening. Engagement with local Black and African American survivor groups and churches is also a key part of community engagement by RLCCP. At Weill Cornell Medicine, specific efforts include expanding practice footprints into more heavily Black and African American communities, recognizing that disparities are a problem to bring awareness to biases, applying for grants to fund disparities research, develop strategies to mitigate the

life stressors of trial participation (*e.g.,* travel), and engage in community outreach. Martin Luther King Jr Community Health, a partnered hospital of UCLA situated in Los Angeles, has expanded efforts to reach Black men through barbershop-based health outreach, recurring health fairs in at-risk neighborhoods, and engaging with key community leaders and stakeholders throughout the area. Their efforts have fallen under two programs, "Man Up" and "Know Your Basics," both conducted by the population health office, with goals aimed at educating, screening, and referring patients for needed health care services. Through these programs annually, an average of 300 men were screened at 43 events (with 8 partnered barbershops), nearly 1,630 members were screened in the community (health fairs, farmers' markets, senior homes, churches), and 102 flu vaccinations were administered at 36 events. Additionally, those men deemed eligible have been offered to enroll in clinical studies aimed at understanding the quality of life (QOL) impacts of PCa in their survivorship journey and developing tools to better communicate their experiences to other Black PCa patients.

This study has limitations, as all information presented is qualitative data collected from patients, advocates, and physicians. While we have presented their perspectives on barriers to enrollment in PCa clinical trials, each group was small ($n = 7$), and therefore we may not have captured all possible perspectives. Additionally, due to the small sample sizes of each group, we were not able to perform quantitative analyses; however, this study was designed specifically to report on qualitative data from each group. We strived for geographic diversity within each group but given each group had 7 participants, it is likely that certain regional-specific barriers were not captured due to a lack of geographic representation. Each group may be subject to inherent biases as well. For instance, the physician group was skewed toward physicians that practice in an academic setting and had a pre-defined interest in clinical trial diversity. The patient group was skewed toward those who did not have prior clinical trial experience; however, this proved useful for understanding why patients may decline to participate in clinical trials. Another limitation was that the caregiver perspective was not included in this study.

5. Conclusions

Despite the lack of racial diversity in PCa clinical trial enrollment, we have learned that significant opportunities exist to better address this unmet need going forward. Sponsors and clinical trial sites must work together to develop targeted and practical strategies to more effectively address barriers that patients, advocates, and physicians are facing to increase diverse enrollment in PCa clinical trials.

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Author contributions

Paul Leger contributed to analysis and interpretation, substantially revised, and critically reviewed the article. Stanley Frencher Jr. contributed to analysis and interpretation, substantially revised, and critically reviewed the article. Jones Nauseef contributed to analysis and interpretation, substantially revised, and critically reviewed the article. Brian Jones contributed to analysis and interpretation, and critically reviewed the article. Mehmet Bilen contributed to analysis and interpretation, and critically reviewed the article. Alan Brown Jr. contributed to analysis and interpretation, and critically reviewed the article. Aminha Ullah contributed to execution, analysis and interpretation, and critically reviewed the article. Shane McDevitt contributed to conception and study design, execution, acquisition of data, analysis and interpretation, drafted, substantially revised, and critically reviewed the article. Che-Kai Tsao contributed to analysis and interpretation, substantially revised, and critically reviewed the article. All authors gave final approval for publication.

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Ethical declaration

This project was deemed exempt by an institutional review board (WCG IRB) because the research only includes interactions involving educational tests, survey procedures, interview procedures, or observations of public behavior; and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects. Regardless, verbal and written informed consent was obtained from each participant.

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