Fact or Myth? Black Patients Do Not Want to Participate in Clinical Trials

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INTRODUCTION: **To assess strategies for optimizing participation of underserved minorities in a blood-based early colorectal cancer detection test study (PREEMPT CRC; NCT04369053) at a hospital serving primarily Black individuals.**

METHODS: **Culturally sensitive, racially congruent research staff approached individuals undergoing average-risk screening colonoscopy. Consent/study procedures were synchronized with clinical appointments. Enrolled and not-enrolled patient characteristics were compared. Recruitment was compared with other study sites.**

RESULTS: **In total, 247 of 509 eligible individuals were enrolled; most were identified as Black (88.7%). No baseline characteristics were associated with participation. Recruitment was high compared with other sites (11th centile).**

DISCUSSION: **Recruitment barriers for Black individuals can be overcome when easy, culturally sensitive access is facilitated.**

KEYWORDS: colorectal cancer; screening; clinical trial; minorities; inclusion; representation; health equity

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INTRODUCTION

Black individuals have been consistently underrepresented in clinical trials despite initiatives to increase recruitment of minority populations (1–5). Lower participation of Black Americans in clinical trials has been historically attributed to distrust borne of abusive practices in medical research (6). Other obstacles limiting minority participation in clinical research include lack of access to clinical trials, lack of minority representation among research staff and healthcare providers, lack of awareness of clinical trials and their purpose, and socioeconomic barriers associated with participation, such as transportation and childcare costs (5,6).

Underrepresentation of minority populations in clinical trials may affect the validity and generalizability of results, as studies may be underpowered to detect potential population differences in efficacy and safety (2–4). Such biased data may also be carried forward into further clinical trials (4). This, and the lack of access to innovative therapies through clinical trials, may exacerbate health inequities (4,7).

In the United States, colorectal cancer (CRC) disproportionately affects minority populations, with a 15% higher incidence and 35% higher death rate among Blacks vs non-Hispanic Whites (8). Factors contributing to worse outcomes in Black individuals include historic differences in screening rates, disparities in access to quality screening and treatment, and potential differences in biological and lifestyle risk factor distribution (9,10). As screening prevents CRC and reduces CRC-related mortality through identification of precancerous lesions and early-stage cancer (10), ensuring adequate representation of disproportionately affected communities in CRC screening studies is critical (8,11,12).

The Prevention of Colorectal Cancer Through Multiomics Blood Test (PREEMPT CRC) study (NCT04369053, clinicaltrials.gov) assessed the efficacy of a new blood-based test for the early detection of CRC. Such a test performed through routine blood draw could potentially boost screening adherence and detection rates in underserved populations. PREEMPT CRC study sites included Grady Memorial Hospital—a large, inner-city, public safety-net hospital affiliated with Morehouse School

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of Medicine, a historically Black College and University (HBCU), with a primarily Black patient (>80%) population.

In this study, we evaluate the facilitation of easy, culturally sensitive study access to eligible individuals at the HBCU site.

METHODS

Recruitment for PREEMPT CRC at Grady Memorial Hospital began on April 1, 2021, and ended on October 31, 2021. Eligible individuals aged 45–75 years undergoing routine average-risk CRC screening colonoscopy were approached by research staff for possible trial participation. All individuals provided informed consent, and the study was approved by the relevant Institutional Review Boards.

The strategies used to facilitate easy, culturally sensitive study access to eligible individuals included the following: (i) individuals' usual healthcare providers coordinated study referrals; (ii) culturally sensitive, racially congruent research staff approached eligible individuals; and (iii) consent/study procedures were synchronized with individuals' preclinical or endoscopic appointments to minimize study-related visits. A screening log was used to record whether eligible individuals chose to participate. Demographic information, including age, gender, race, body mass index, and religion, were abstracted from electronic medical records.

Enrolled individuals provided a blood sample through a standard blood draw before bowel preparation for standard-of-care screening colonoscopy. The objectives of PREEMPT CRC were to assess the sensitivity and specificity of the CRC early detection blood test.

PREEMPT CRC data were linked to the 2020 American Community Survey (5-Year Estimates; https://www.census.gov/data/developers/data-sets/acs-5year.html) to examine tract-level variables such as education and median household income. Social Explorer (Bronxville, NY) was used to download the 2020 American Community Survey (5-Year Estimates) data, which were merged with PREEMPT CRC data using Federal Information Processing Standards (FIPS) as the unique identifier. US Census Geocoder (https://geocoding.geo.census.gov/geocoder/) was used to batch and generate FIPS codes for 551 records. Of these, 466 records were successfully matched; 79.4% were exact matches and 20.6% were nonexact. There were 84 missing FIPS codes because of missing or incomplete addresses.

Descriptive statistics were calculated for eligible individuals. Means and SDs were used for continuous variables, and frequencies with percentages were used for categorical variables. Two-sample *t*-tests were used to compare the means and medians of the continuous variables. The Pearson χ^2 test was used for categorical variables. All data analyses were performed using STATA version 16 (StataCorp, College Station, TX).

Ethics approval and consent to participate: PREEMPT CRC (NCT04369053, clinicaltrials.gov) received approval from the relevant Ethics Committees and Institutional Review Boards. At the Morehouse School of Medicine, approval was given through Institutional Review Board Protocol # 20200609. All individuals gave informed consent for participation in the study.

RESULTS

Of 509 eligible individuals at the HBCU site, 247 were enrolled into the study and received a blood draw before their scheduled colonoscopy, placing the site in the top 11th centile for enrollment across all study sites.

Sociodemographic characteristics for enrolled and not-enrolled individuals at the HBCU were similar (Table 1); statistical analysis did not identify factors that significantly affected participation in the clinical study ($P > 0.05$ for all comparisons).

DISCUSSION

Our study demonstrates that facilitating easy, culturally sensitive study access to Black individuals at their usual site of care is an effective recruitment strategy. Our approach—coordinating study referrals with individuals' usual providers; having culturally sensitive, racially congruent research staff approach individuals; and synchronizing consent and study procedures with other clinical visits—was based on previously recognized factors that contribute to inadequate enrollment of underserved minority populations in clinical trials (5,13).

In this study, sociodemographic data revealed no significant differences between individuals who did and did not choose to participate in PREEMPT CRC, suggesting that gender, age, body mass index, race, marital status, religion (Christianity), and insurance type did not affect willingness or ability to participate.

Our findings are consistent with previously reported survey results indicating that reducing logistical barriers and diversifying research staff can lead to successful recruitment of underserved minority individuals (7,14). Additional recruitment drivers that have been shown to further boost recruitment include cost coverage and increase participant awareness of the need for diversity in clinical trials, their purpose, and the potential health benefits associated with participation (7,14).

Our data suggest that facilitating easy, culturally sensitive access to clinical studies for Black individuals can overcome traditional barriers to participation, ensuring adequate representation and improved health equity.

CONFLICTS OF INTEREST

Guarantor of the article: Julia J. Liu, MD.

Specific author contributions: K.M.: Conceptualization, Data curation, Investigation, Writing—original draft, Writing—review and editing. F.F.: Conceptualization, Data Curation, Methodology, Formal Analysis, Investigation, Writing—review and editing. R.K.: Investigation, Project administration, Supervision, Validation, Writing—review and editing. E.E.: Investigation, Writing—review and editing. L.C.L.: Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Writing—review and editing. L.B.: Conceptualization, Writing—review and editing. C.X.: Conceptualization, Resources, Supervision, Writing—review and editing. S.W.: Data curation, Formal analysis, Writing—review and editing. R.M.A.: Methodology, Formal Analysis, Investigation, Writing—review and editing. P.P.: Investigation, Project administration, Resources, Writing—review and editing. Theodore Levin: Investigation, Writing—review and editing. A.S.: Investigation, Methodology, Writing—original draft, Writing—review and editing. J.J.L.: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing—original draft, Writing—review and editing.

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Table 1. Baseline participant sociodemographic characteristics

	Not enrolled N = 262	Enrolled N = 247	*P* value
Age, yr (mean ± SD)	57.7 ± 7.2	57.4 ± 7.1	0.86
Race, n (%)			0.70
Black or African American	230 (87.8%)	219 (88.7%)	
Hispanic or Latino	15 (5.7%)	12 (4.9%)	
White	14 (5.3%)	11 (4.5%)	
Other	2 (0.8%)	4 (1.6%)	
Unknown	1 (0.4%)	1 (0.4%)	
Female, n (%)	154 (59.2%)	144 (58.3%)	0.79
BMI, kg/m^2 (mean ± SD)	31.3 ± 8.2	31.9 ± 8.4	0.40
Marital status, n (%)			0.70
Divorced	44 (16.9%)	43 (17.4%)	
Married	40 (15.4%)	47 (19.0%)	
Separated	24 (9.2%)	23 (9.3%)	
Single	130 (50.0%)	117 (47.4%)	
Unknown/other	8 (3.1%)	4 (1.6%)	
Widowed	14 (5.4%)	13 (5.3%)	
Religion, n (%)			0.38
Christian	194 (74.6%)	190 (76.9%)	
None/no preference	44 (16.9%)	32 (12.9%)	
Other/unknown	22 (8.5%)	25 (10.1%)	
No college (%)	39.9 ± 14.8	42.1 ± 15.0	0.13
Any college (%)	60.1 ± 14.8	57.9 ± 15.0	0.13
Median household income, (Q1, Q3), $	47,278 (32,500, 65,121)	45,333 (35,313, 62,543)	0.82
Insurance status, n (%)			0.98
Medicare/Medicaid	69 (26.6%)	61 (26.3%)	
None	115 (44.4%)	105 (45.3%)	
Private	75 (29.0%)	66 (28.4%)	

BMI, body mass index; Q1, 1st quartile; Q3, 3rd quartile.

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Availability of data and materials: The data underlying this article cannot be shared publicly due to the privacy of individuals who participated in the study.

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