Research Paper

PAIN®

Race-based reporting and participation of Black individuals in registered pain clinical trials, United States, 2000 to 2019

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Abstract

There are numerous, well-established racial disparities in the management of pain. The degree to which these are evident at the stage of conducting clinical trials is unknown. To address this knowledge gap, we examined race-based reporting, participation of Black individuals, and the factors associated with reporting and participation in pain clinical trials in the United States. Data were extracted from Clinicaltrials.gov and published articles. One thousand two hundred trials met our inclusion criteria; 482 (40.2%) reported participant race. More recent, publicly funded, and larger trials were more likely to report race. Of 82,468 participants included in pain clinical trials that reported race, 15,101 were Black individuals (18.3%). Participation of Black individuals was significantly associated with pain type (ß = +27% in cardiovascular disease pain compared with acute pain, $P < 0.05$), study population (ß = +33% and +7% in pain in minoritized populations and women, respectively, compared with general population, $P < 0.05$), pain intervention (ß = +7.5% for trials of opioid interventions compared with nonopioid interventions, $P < 0.05$), and a diverse team of investigators (ß = +8.0% for studies incorporating a visible non-White investigator compared with those that did not, $P < 0.05$). Our results indicate that representation of Black participants in pain clinical trials generally aligns with national demographics in the United States. Increased representation corresponds with health conditions more prevalent among Black individuals (eg, cardiovascular disease) and with a diverse study team composition. Despite these encouraging results, less than half of pain trials reported race, which introduces potential publication bias and limits external validity.

Keywords: Racial groups, Ethnicity, Representation, Diversity, Clinical trials, Pain

1. Introduction

Racial discrimination in health care has been widely documented across a range of medical interventions,[7,25,39,50] including the management of pain (eg, inequitable prescribing of analgesic medications).[3,20,38,51] Racism in pain management is further demonstrated by false beliefs regarding biological differences based on race (eg, Black people have thicker skin or Black bodies feel less pain than White bodies).[25,31,66] By contrast, mounting evidence suggests that Black/African Americans may experience increased pain sensitivity compared with their White counterparts—an effect mediated partly by chronic stress associated with racial discrimination and learned behavioural responses to historic mistreatment.[32,37]

Before implementation in patients, interventions for pain are tested in clinical trials in research participants. Racial diversity in clinical trials is vital for generalizing results and ensuring equitable benefits to medical advances.[64] However, racial diversity, particularly participation of Black individuals in the United States, may be low in pain clinical trials due to a variety of factors, including distrust in research related to past experimentation, lack of health insurance, comorbidities (used as exclusion criteria in clinical trials), and costs to participate (eg, transportation, parking, and missed work).[8,12,36,57]

Demonstrating a commitment to participant diversity in clinical trials, the National Institutes of Health (NIH), US Food and Drug Administration (FDA), Agency for Health Research and Quality, and Centers for Disease Control and Prevention have developed guidelines advocating for greater inclusivity and diversity.[19,45,62] Despite these efforts, failure to comply with race-based reporting guidelines and the underrepresentation of Black, Indigenous, and People of Colour (BIPOC) in clinical trials remains a major societal issue.[4,6,9,19,24,28,44,58] Several frameworks to overcome barriers of racial disparities in clinical trials have been addressed.[12,22,67] Adherence to guidelines and racial diversity in pain clinical trials has not, however, been previously examined. The goal of this study was to quantify the reporting of race, participation of Black individuals, and potential factors associated with race-based reporting and participation in pain clinical trials in the United States. Our primary hypothesis was that the representation of

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PAIN 00 (2023) 1–9

http://dx.doi.org/10.1097/j.pain.0000000000002893

Black individuals in pain clinical trials would be lower compared with that of national averages.

2.Methods

2.1. Identification of registered pain clinical trials and study inclusion/exclusion criteria

On July 3, 2020, the Aggregate Analysis of ClinicalTrials.gov (AACT) was downloaded. A query was performed to identify clinical trials listing "pain" in their registration as the "condition" of interest. Other inclusion criteria included the following: interventional trials (as identified by study investigators), English language, a start date from 2000 to 2019, and registered in the United States. Because of their leadership in race reporting guidelines, the United States was the focus of this investigation. Trials were excluded if they did not address signs and symptoms of pain. For example, trials addressing opioid-induced constipation (eg, NCT01993940), but were not directed at pain management, were excluded. Trials were reviewed for inclusion by A.K.V. and J.L.K.K. for suitability, both of whom were blinded to trial details pertaining to race-based reporting. Discrepancies were discussed until consensus was reached.

2.2. Data extraction

Information pertaining to trial characteristics (eg, sponsorship) was extracted from the AACT database. A complete list

Table 1

Extracted data elements in interventional pain clinical trials.

Variable name	Definition	Source	Derived categories
Race-based reporting	Any racial information present in text or demographics table	clinicaltrials.gov and pubmed.com	Yes/no
Total number of Black participants	Total number of Black participants included (among only studies where race was reported)	Table "baseline_measurements" from ACCT (https://aact.ctti-clinicaltrials.org/data_dictionary)	Count
Total number of participants	Total number of participants per clinical trial	Table "baseline_counts" and "studies" from AACT (https://aact.ctti-clinicaltrials.org/data_dictionary)	Count
Type of pain	International Association for the Study of Pain*	Tables "brief_summaries" and "conditions" from AACT (https://aact.ctti-clinicaltrials.org/data_dictionary)	Acute, chronic, cancer, cardiovascular, palliative
Pain intervention	Whether the trial intervention was an opioid or nonopioid substance†	Tables "brief_summaries" and "conditions" from AACT (https://aact.ctti-clinicaltrials.org/data_dictionary)	Opioids/nonopioids
Study population	Primary study population as defined by inclusion/exclusion criteria for each trial	Tables "brief_summaries" and "conditions" from AACT (https://aact.ctti-clinicaltrials.org/data_dictionary)	Elderly individuals (65 years and older), female only, healthy, children (aged 4-12 years), minority only, and veterans, or NA if the trial did not specify
Diverse team of investigators	Subjective determination of trial investigator as Black/Indigenous/People of colour (BIPOC or "diverse") or Non-BIPOC, using methods as previously described‡	Table "facility_investigators" from AACT (https://aact.ctti-clinicaltrials.org/data_dictionary)	Yes/no
Funding sponsor	Primary funding sponsor (ie, funded by the NIH, US Federal, others)	Table "sponsors" from AACT (https://aact.ctti-clinicaltrials.org/data_dictionary)	Industry/nonindustry
Funding of clinical trial facilities	Type of funding for clinical trial facility	Homeland infrastructure foundation-level data (HIFLD) (https://hifld-geoplatform.opendata.arcgis.com/)	Government/nongovernment
Trials across different states	If a trial setting was in more than 1 state, this was assigned as "multiple." Otherwise, assigned as "single."	Table "facilities" from AACT (https://aact.ctti-clinicaltrials.org/data_dictionary)	Multiple/single
Trial start year	Year in which the trial started	Table "studies" from AACT (https://aact.ctti-clinicaltrials.org/data_dictionary)	Quartile of start year
Trial phase	The phase of each trial (phase 1, 1/2, 2, 2/3, 3, and 4)	Table "studies" from AACT (https://aact.ctti-clinicaltrials.org/data_dictionary)	Early/late

* Duration of pain symptoms greater than 3 mo was characterized as chronic (and acute <3 mo). Conditions classically associated with long-term pain symptoms, such as diabetic neuropathies, were also defined as chronic. Cancer, cardiovascular (ie, chest), and palliative pain were characterized based on the study objective provided in the trial registration and from the abstract in published trials.

† To corroborate this classification, pharmacological interventions were cross-referenced with a list of common active opioids (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/list-opioids.html).

‡ Perceived race of investigators was performed by searching for their image through official verifiable sites such as LinkedIn and then determined by AK.

AACT, Aggregate Analysis of ClinicalTrials.org.

of variables is provided in **Table 1**. If available, participant race was extracted directly from the AACT; otherwise, participant racial information was manually searched in PubMed using the clinical trial registration number. We also manually evaluated the perceived race of trial investigators. This was determined through online searches of investigator photographs based on their names listed in the AACT database. A similar approach has been previously adopted.[65] AK made the final determination of race (White or non-White).

2.3. Statistical analysis

Race-based reporting (yes/no) and percentage of Black individuals served as primary outcomes. The focus was on Black participants due to the inconsistent nature of reporting other races. For the outcome of participation of Black individuals (expressed as a percentage), bivariable and multivariable linear regression analyses were performed; for race-based reporting, bivariable and multivariable logistic regressions were used. $P < 0.05$ was considered statistically significant. Data extraction from the AACT database was conducted using Structured Query Language, and analyses were conducted using R Statistical software, version 4.0.2. Code and data from this study are available at https://github.com/AnhKhoaVo/Race_in_Pain_Clinical_Trials.

3. Results

3.1. Descriptive summary

The AACT database resulted in 12,688 trials on "pain" as the "condition." Of those, 1433 trials reported results. The remaining 11,255 trials were manually searched in PubMed, which yielded, 1145 trial publications with results. A total of 2578 trials with reported results were found. However, accounting for other inclusion/exclusion criteria, 1200 trials were included in our analysis; 482 trials (40.2%) of which reported information pertaining to race (**Table 2**), with 428 trials (35.6%) specifically identifying participation among Black individuals (**Table 3**). In these 428 trials, 15,101 of 82,468 (18.3%) participants were Black individuals (**Table 3**). Acute pain trials accounted for 210 of 428 total trials (49%), and most pain trials focused on the general population (283 of 428 total trials, 66.1%) (**Table 3**).

3.2. Race-based reporting in pain clinical trials

The results from logistic regression for race-based reporting in included studies are summarized in **Table 4**. In bivariable analysis, the total number of participants, start year, and multistate trials were significantly associated with reporting the race of study participants. Multivariable analysis revealed that the number of participants, trial funding sponsor, and trial star year were significantly associated with studies reporting on race: race-

Table 2

Characteristics of included pain interventional studies.

Study factor	Total no. of studies	No. of studies reporting race (%)	No. of studies not reporting race (%)
All trials	1200	482 (40.2)	718 (59.8)
Total participants	1200		
<33	—	105 (35)	195 (65)
33-75	—	111 (36)	197 (64)
76-161	—	110 (37.5)	183 (62.5)
>161	—	156 (52.1)	143 (47.9)
Funding sponsor	1200		
Industry	—	129 (41.7)	180 (58.3)
Nonindustry	—	353 (36.9)	538 (63.1)
Trial start year	1200		
2000-2004	—	17 (25.7)	49 (74.3)
2005-2009	—	99 (30.1)	229 (69.9)
2010-2014	—	218 (41.2)	311 (58.8)
2015-2019	—	148 (53.4)	129 (46.6)
Trial phase	701		
Early (phase I/II)	—	91 (38.2)	147 (61.8)
Late (phase III/IV)	—	191 (41.2)	272 (58.5)
NA	499	200	299
Diverse team of investigators	916		
No	—	288 (39.6)	439 (60.4)
Yes	—	70 (37)	119 (63)
NA	284	124	160
Trials across different states	1177		
Single state	—	314 (37.4)	524 (62.6)
Multiple states	—	159 (46.9)	180 (53.1)
NA	23	9	14
Funding of trial facilities	1132		
Government	—	107 (43.4)	139 (56.6)
Nongovernment	—	351 (39.6)	535 (60.4)
NA	68	24	44

Table 3

Characteristics of pain clinical trials that reported Black participation.

Study factor	Total no. of studies that reported participation of Black individuals	Total no. of study participants	Black individual participation (%)	Non-Black individual participation (%)
All trials	428	82,468	15,101 (18.3)	67,367 (81.7)
Type of pain				
Acute	210	32,785	5348 (16.3)	27,437 (83.7)
Chronic	174	28,357	5086 (17.9)	23,271 (82.1)
Cancer	33	4621	447 (9.6)	4180 (90.4)
Cardiovascular	7	10,140	2319 (22.8)	7821 (77.2)
Palliative	4	6565	1901 (29)	4664 (71)
Study population				
Elderly	11	1637	347 (21.2)	1290 (78.8)
General	283	65,477	11,709 (17.9)	53,768 (82.1)
Pediatric	33	3332	375 (11.3)	2957 (88.7)
Minority	4	810	390 (48.1)	420 (51.9)
Veterans	25	3726	740 (19.9)	2986 (80.1)
Women only	72	7486	1540 (20.6)	5946 (79.4)
Pain intervention				
Opioid	79	13,921	2689 (19.3)	11,232 (80.7)
Nonopioid	349	68,547	12,412 (18.1)	56,135 (81.9)
Diverse team of investigators				
Yes	61	6389	1642 (25.6)	4747 (74.4)
No	252	49,086	9667 (19.6)	39,419 (80.4)
NA	115	26,993	3792	23,201
Funding sponsor				
Industry	124	31,249	4146 (13.2)	27,103 (86.8)
Nonindustry	304	51,219	10,955 (21.3)	40,264 (78.7)
Trials across different states				
One state	271	35,315	7151 (20.2)	28,164 (79.8)
Multiple states	148	44,945	7799 (17.4)	37,146 (82.6)
NA	9	2208	151	2057
Trial start year				
2000-2004	9	2766	393 (14.2)	2373 (85.8)
2005-2009	83	31,311	5680 (18.1)	25,631 (81.9)
2010-2014	198	32,449	6202 (19.1)	26,247 (80.9)
2015-2019	138	15,942	2826 (17.7)	13,116 (82.3)
Trial phase				
Early (phase I/II)	79	7800	1205 (15.4)	6595 (84.6)
Late (phase III/IV)	177	47,628	7622 (16)	40,006 (84)
NA	172	27,040	6274	20,766
Funding of trial facilities				
Government	99	14,950	3795 (25.4)	11,155 (74.6)
Nongovernment	303	59,369	10,452 (17.6)	48,917 (82.4)
NA	26	8149	854	7295

based reporting was more likely in larger, more recent, and publicly funded (nonindustry) trials (**Table 4**).

3.3. Participation of Black individuals in pain clinical trials

Results from bivariable and multivariable linear regression analyses for the participation of Black individuals are summarized in **Table 5**. In bivariable analysis, the percentage of Black participants enrolled in cancer pain clinical trials was significantly lower (−6.5%, $P = 0.033$) compared with that in acute pain trials. Conversely, trials focused on cardiovascular disease pain (eg, angina) reported significantly greater participation of Black individuals (+27%, $P < 0.001$) compared with that in acute pain trials. Compared with trials with no special population of interest, those addressing pain in minoritized populations enrolled a significantly higher proportion of Black participants (+33%, $P < 0.001$). There was also a trend for trials including only women to enroll more Black participants (+4%, $P = 0.065$). Trials with federal sources of funding (compared to industry) and a team of diverse investigators (compared with only White investigators) enrolled a higher proportion of Black participants. In the multivariable analysis, cardiovascular and chronic pain trials, trials focused in women, trials of opioid interventions, and those with a diverse study team remained significantly associated with participation of Black individuals (**Table 5**).

Table 4

Factors associated with race-based reporting: logistic regression analysis.

Variables	Bivariable		Multivariable	
	OR (95% CI)	*P*	OR (95% CI)	*P*
Total no. of participants (N = 1200)				
<33	—		—	
33–75	1.05 (0.75-1.46)	0.8	0.79 (0.45-1.37)	0.4
76-161	1.12 (0.80-1.56)	0.5	1.49 (0.87-2.56)	0.15
>161	2.03 (1.46-2.82)	**<0.001**	3.63 (1.96-6.85)	**<0.001**
Funding sponsor (N = 1200)				
Industry	—		—	
Nonindustry	0.92 (0.70-1.19)	0.5	2.75 (1.50-5.22)	**0.001**
Trial start year (N = 1200)				
2000-2004	—		—	
2005-2009	1.25 (0.70-2.33)	0.5	1.99 (0.86-4.94)	0.12
2010-2014	2.02 (1.16-3.70)	**0.017**	3.00 (1.34-7.25)	**0.01**
2015-2019	3.31 (1.85-6.17)	**<0.001**	5.34 (2.17-14.0)	**<0.001**
Trial phase (N = 701)				
Early (phase I/II)	—		—	
Late (phase III/IV)	1.13 (0.82-1.57)	0.4	0.83 (0.55-1.27)	0.4
Diverse team of investigators (N = 916)				
No	—		—	
Yes	0.90 (0.64-1.24)	0.5	1.28 (0.74-2.22)	0.4
Trials across different states (N = 1177)				
Single state	—		—	
Multiple states	1.47 (1.14-1.90)	**0.003**	1.28 (0.74-2.22)	0.4
Funding of trial facilities (N = 1132)				
Government	—		—	
Nongovernment	0.85 (0.64-1.14)	0.3	0.81 (0.48-1.37)	0.4

CI, confidence interval; OR, odds ratio. Bold indicates $P<0.05$.

4. Discussion

Overall, the participation of Black individuals in pain clinicals trials over a 20-year period paralleled population demographics in the United States and general clinical trials demographics (approximately 13% to 16%).[15,63] Participation of Black individuals was highest in trials aimed at interventions for the management of cardiovascular pain, opioid therapies, and in those conducted in minority populations and women. The diversity of the study team had a significant impact on the participation of Black individuals, such that trials with at least 1 perceived BIPOC investigator was associated with an increased representation. The lack of reporting remains a major issue, with only 40% of trials providing a breakdown of participant enrollment by race.

Numerous investigations, including those addressing participation in cancer, vaccine, acute leukemia, and heart failure clinical trials, have documented low rates of compliance with the reporting of race.[17,23,36,59] In close agreement with our results, only 43% of more than 20,000 general clinical trials registered on ClinicalTrials.gov have adequately reported the race of participants. This figure only marginally improves by focusing on trials published in top-tier medical journals.[1,61] Our analysis also identified a number of predictors of reporting race in included pain studies that have been documented elsewhere, including sample size and year of publication, with the latter reflecting a trend towards recent improvements.[6,34,54,61] Also in alignment with a recent study that examined race-based reporting and racial representation over 20 years in the United States (not specific to pain trials), significantly lower race reporting was identified in industry-funded trials compared with that in those that were publicly funded.[61] This could be due to the reporting requirements for publicly funded trials, per the NIH Revitalization Act.[45]

A number of factors may contribute to why race continues to go unreported in clinical trials for pain, despite a clear mandate.[19,46] Trial investigators may either neglect to collect requisite information pertaining to participant race—and thereby cannot report it—or collected these data and withheld it from published results. In both cases, failure to report may reflect lack of awareness on part of investigators of existing guidelines and inadequate recognition of the value of racial diversity in clinical trials (eg, promoting equity, study generalizability, and building trust in racially oppressed groups). Trials that obtained data on race, but did not report it, may also be concerned for the implications of underrepresenting racial minorities populations (eg, issues raised during peer review). In these cases, research ethics boards, regulators, and academic publishers should ensure that race information is adequately reported regardless of enrollment outcomes. The benefits of race reporting not only advance the work of trial investigators for the broader population but also facilitate self-determination in the races represented. Updated guidance from the American Medical Association on reporting of race and ethnicity in clinical and scientific publications may inform these efforts, as well as efforts to decenter Whiteness in research.[16,18]

Recent scholarship has called attention to the importance of race consciousness in medical research and practice.[11,41] However, prevailing assumptions regarding racial data tend toward treating race as a covariate or control to explain differences among racial groups as inherent, fixed biological characteristics (eg, age).[13,56] This results from longstanding flaws

Table 5

Factors associated with participation of Black individuals (% Black): linear regression.

Variables	Bivariable		Multivariable	
	Beta (95% CI)	*P*	Beta (95% CI)	*P*
Type of pain (N = 428)				
Acute	—		—	
Chronic	2.4 (−0.85 to 5.6)	0.15	7.6 (0.35 to 15)	**0.040**
Cancer	−6.5 (−12 to −0.54)	**0.033**	−1.5 (−11 to 7.8)	0.7
Cardiovascular	27 (15 to 39)	**<0.001**	30 (5.1 to 54)	**0.018**
Palliative	−5.3 (−21 to 11)	0.5	−6.3 (−39 to 26)	0.7
Study population (N = 428)				
General	—		—	
Elderly	4.2 (−5.7 to 14)	0.4	−2.7 (−18 to 12)	0.7
Pediatric	−1.2 (−7.1 to 4.7)	0.7	−2.8 (−12 to 6.7)	0.6
Minority	33 (17 to 50)	**<0.001**	—	—
Veterans	3.8 (−2.9 to 10)	0.3	10.0 (−3.9 to 24)	0.2
Women only	4.0 (−0.25 to 8.2)	0.065	7.9 (1.1 to 15)	**0.023**
Pain intervention (N = 428)				
Nonopioid	—		—	
Opioid	3.3 (−0.73 to 7.4)	0.11	7.5 (0.78 to 14)	**0.029**
Funding sponsor (N = 428)				
Industry	—		—	
Nonindustry	4.6 (1.2 to 8.1)	**0.008**	0.25 (−8.2 to 8.7)	>0.9
Starting year (N = 428)				
2000-2004	—		—	
2005-2009	−5.1 (−17 to 6.3)	0.4	−3.5 (−22 to 15)	0.7
2010-2014	−0.6 (−12 to 10)	>0.9	−0.37 (−17 to 17)	>0.9
2015-2019	−1.1 (−12 to 10)	0.8	1.5 (−16 to 19)	0.9
Trial phase (N = 256)				
Early (phase I/II)	—		—	
Late (phase III/IV)	0.26 (−3.7 to 4.2)	0.9	1.1 (−4.9 to 7.1)	0.7
Diverse team of investigators (N = 313)				
No	—		—	
Yes	5.6 (0.88 to 10)	**0.020**	8.0 (1.5 to 14)	**0.016**
Trials across different states (N = 419)				
Single state	—		—	
Multiple states	−1.4 (−4.7 to 2.0)	0.4	−0.44 (−7.7 to 6.8)	>0.9
Funding of trial facilities (N = 402)				
Government	—		—	
Nongovernment	−3.4 (−7.2 to 0.46)	0.085	−1.3 (−9.1 to 6.5)	0.7

CI, confidence interval. Bold indicates $P<0.05$.

in research and education that essentialize racial health inequities as arising from genetic variation, rather than as a consequence of differential environmental exposure.[19,64] Reporting race does not necessitate the analysis of trial outcomes by race; indeed, we and others advise against using race to classify diverse clinical or biological outcomes.[68] We do, however, emphasize the importance of maintaining—and increasing—diversity in clinical trials to promote generalizability across people with different experiences of racialization, to ensure the equitable benefits of clinical research, and to increase confidence in biomedical research and healthcare institutions.[64] Interventions regarding the use of race in clinical trials can target investigators' conceptualization of race as a risk marker rather than as a risk factor, similar to socioeconomic status, and to emphasize the impact of structural racism as a determinant of divergent outcomes. In addition, there is also a growing movement within pain research calling for antiracism. In this framework, several commitments were highlighted, including education (eg, cultural humility and implicit bias), inclusion (eg, changes in institutional culture), policy (eg, journal guidelines), research design (eg, biopsychosocial narrative, race as sociopolitical construct), dissemination of research (intentional language), and ongoing evaluation (eg, regular assessment).[27,35,42]

In conjunction with low levels of reporting of race, previous investigations have demonstrated the underrepresentation of BIPOC individuals in clinical trials.[6,9,28,36,58] This has been attributed to a variety of sociocultural factors, including the lack of access to health care, lower levels of health insurance, distrust in health care, and access to transportation.[2,12,49,55,57] Moreover, stemming from a long-troubled past in medicine and cultural memory of experimentation, including experimentation on the enslaved, disinterment of Black bodies for use in anatomy lessons, forced sterilizations of Black women, segregated hospitals that involved lower quality of care for Black patients, and the Tuskegee syphilis study, mistrust in research may also limit participation.[26,30,33,47,53,55] In contrast to our hypothesis, we observed overall participation on par with the racial breakdown of the United States (ie, ~13% to 16%).[15,63]

In fact, representation of Black individuals was higher compared with national demographics for several pain conditions. These results correspond with elevated incidence of cardiovascular disease and chronic pain in the Black population.[5,21,43,60] Studies addressing pain specifically in racially minoritized populations enrolled a greater number of Black participants—not particularly surprising, given that Black individuals represent a target group. Black representation was also higher in pain trials focused on women and opioids. This seemingly points to a paradox between research and clinical settings, where individuals who are Black are more likely to be involved in trials but less likely to be managed with opioids in real-world settings compared with their White counterparts.[3,20,51]

Collectively, these results raise the question as to why participation in pain trials has achieved or exceeded the national representation, whereas other health conditions often fail to achieve racial diversity (eg, cancer)[9,36] fail to do so? One possibility is that, after decades of research identifying racial disparities in managing pain, coupled with knowledge emphasizing that pain is a "biopsychosocial" phenomenon, researchers have adopted inclusive participant recruitment practices. In support of such a theory, other health conditions that prioritize a biopsychosocial model of disease (eg, depression) have also demonstrated an adequate representation of BIPOC in clinical trials.[52] Another potential explanation could be that compensation for participation in studies may differentially affect low-income populations, though we were not able to collect data on study compensation.[14]

In addition to pain and intervention type and study population, perceived racial diversity among the investigator team significantly increased representation of Black patients in included trials. This observation corresponds with findings from a recent study addressing participation in heart failure trials, in which increased female representation on the study team was associated with an 8.4% increase in BIPOC enrollment.[40,65] The value of such an observation cannot be minimized: to facilitate diversity in clinical trials, diversifying investigators represents a critical step. In our analysis, only 14% of trials were classified as diverse. Recent reports have indicated that less than 3 percent of NIH trial investigators are BIPOC.[48] Diversity among leadership teams could improve diversity in participation due to connection with the language, experiences, and attitudes of the target participants.[10,40] Thus, funders and investigators should seek to support, promote, and invest in diverse mentees and collaborators both to advance equity and to improve the quality of the science.

Although our findings regarding racial inclusivity in pain clinical trials are encouraging, there are limitations to consider. Firstly, our study included 1200 registered clinical trials reporting results and conducted in the United States. Research not registered, unreported, and/or recruiting participants outside of the United States may be less representative of BIPOC participation. We were also solely focused on Black participation, which means that our findings cannot be generalized to representation of other races in pain clinical trials. Thirdly, we acknowledge that investigator race was determined subjectively and may have introduced bias and misclassification. However, a previous study has adopted this similar approach.[65] Our protocol also raises an important point regarding whether racial demographics are self-assigned or socially assigned: the former conveys group belonging, whereas the latter may indicate experience of racialization.[29] Finally, our search of the registered trials was limited to trials that identified "pain" as the "condition" in clinical trial registration. This will have led to the exclusion of studies that were addressing pain but identified using other terms (eg, arthritis). While a more comprehensive search strategy may have yielded more trials, >12,000 trials were initially queried, with a manual search of >11,000 trials performed in PubMed, from which a large sample (n = 1200) was included in the final analysis.

5. Conclusion

Overall rates of reporting race remain low in pain clinical trials; however, the proportion of those participating that are Black aligns with national averages (approximately 13% to 16%). This broadly demonstrates a level of equitable participation achieved in pain clinical trials in the United States, which may reflect the widespread adoption of the biopsychosocial model of pain. Trials aiming to reach equitable representation of Black participants should consider a diverse study team composition.

Conflict of interest statement

The authors have no conflict of interest to declare.

Acknowledgements

This work was funded by a Natural Sciences and Engineering Research Council of Canada (NSERC) Discovery Grant. JC is a Tier 2 Canada Research Chair and Michael Smith Health Research BC Scholar.

Article history:
Received 30 August 2022
Received in revised form 15 December 2022
Accepted 10 January 2023
Available online 17 April 2023

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