


RESEARCH LETTER

Trends in Hypertension Clinical Trials Focused on Interventions Specific for Black Adults: An Analysis of ClinicalTrials.gov

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Representation of Black adults is important in the design and enrollment of hypertension trials. The SPRINT (Systolic Blood Pressure Intervention Trial), for example, enrolled 31% self-reported Black participants, which improved generalizability and race/ethnicity treatment-effect estimation.¹ Representation alone does not replace the need for trials to be designed, and interventions tested, that consider hypertension specific to the context of the Black American experience.² Black adults in the United States face greater rates of cardiovascular disease, largely mediated through higher prevalence of hypertension compared with White counterparts. However, race is not a discrete biological category, but a social construct. This categorization impacts trial recruitment, retention, and environmental interactions, all of which impact clinical response to medical interventions.

Interventions designed for, and tested in, Black American adults, such as BARBER-2 (Blood-Pressure Reduction in Black Barbershops) and FAITH (Faith-Based Approaches in the Treatment of Hypertension) randomized trials, are needed to address disparities in hypertension with consideration of the unique societal context of Black Americans.^{3,4} While there are key published trials enrolling only Black participants, the number of trials planned, running, or never published is unknown. The objective of this report was to determine the proportion of registered hypertension trials in ClinicalTrials.gov designed for and tested in

exclusively self-identified Black Americans from 2009 through 2018.

All data used for this report are publicly available at ClinicalTrials.gov.

ClinicalTrials.gov was queried to extract US-based interventional trials registered from January 1, 2009 to December 31, 2018. Trials were selected using the medical subject headings terms “hypertension” and “blood pressure” in the condition or disease field with characteristics abstracted by automated parsing of the ClinicalTrials.gov-generated list. Title, descriptive terms, and outcome measure fields were queried for “Black” and “African American” to identify candidate hypertension trials, which were then manually reviewed. Trials were deemed Black American-specific if only Black participants were enrolled or planned for enrollment based upon inclusion criteria, or explicitly noted in trial design when inclusion criterion was lacking. Trials that recruited specifically non-Black participants were excluded. Fisher exact test was used for between-group differences. This study did not require institutional review board approval because all data were acquired from the public domain.

Among hypertension trials registered from 2009 to 2018 overall, 956 met inclusion criteria (Table).

The annual number of hypertension trials registered in ClinicalTrials.gov increased from 77 (2009) to 146 (2018). Fifty-two (5.4%) trials reported enrolling exclusively Black American adults. The percentage that

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Table 1. Characteristics of Clinical Trials

	All Clinical Trials	Non–Race-Specific	Black American–Specific
Number of clinical trials (row %)	956	904 (94.6)	52 (5.4)
Percentage of US population in 2018			13.4%
Status			
In process (not yet recruiting, recruiting, active not recruiting, enrolling by invitation)		204 (22.6)	16 (30.8)
Discontinued (withdrawn, terminated, suspended)		146 (16.2)	4 (7.7)
Completed		513 (56.7)	29 (55.8)
Unspecified (missing or “NA”)		41 (4.5)	3 (5.8)
Multisite			
Yes (%)		166 (18.4)	11 (21.2)
Phase			
Early Phase 1/Phase 1		84 (9.3)	4 (7.7)
Phase 2		132 (14.6)	6 (11.5)
Phase 3		46 (5.1)	2 (3.8)
Phase 4		107 (11.8)	5 (9.6)
Did not meet specific FDA criteria		535 (59.2)	35 (67.3)
Funder			
Public		181 (20.0)	18 (34.6)
Industry		208 (23.0)	7 (13.5)
Other		515 (57.0)	27 (51.9)
Intervention type			
Pharmacologic (includes biological)		351 (38.8)	16 (30.8)
Procedural intervention/device		126 (13.9)	0 (0.0)
Behavioral/lifestyle		205 (22.7)	28 (53.8)
Other		222 (24.6)	8 (15.4)
Reported results		223 (24.7)	7 (13.5)
Publication		195 (21.6)	5 (9.6)
New trials by y			
2009	77	74	3
2010	91	84	7
2011	86	78	8
2012	86	84	2
2013	92	89	3
2014	95	89	6
2015	86	79	7
2016	97	95	2
2017	100	95	5
2018	146	137	9

Non–race-specific: in this context refers to a study population that attempts to recruit and represent a sample of the public without any specific race or ethnic emphasis. Percentages are based upon column totals. Total percentages for studies by race-specific vs non–race-specific may be not exactly equal 100% because of rounding. Trials were extracted from ClinicalTrials.gov on February 2, 2020. Analysis was performed in R 3.5.3. FDA indicates US Food and Drug Administration; and NA, not available.

were Black American–specific was 3.9% (3) in 2009, and 6.2% (9) in 2018 ($P=0.55$). Additionally, the ratio of African American–specific to non–race-specific trials was 0.04 in 2009 and 0.06 in 2018.

Non–race-specific trials were more frequently non-publicly sponsored (80.0% versus 65.4%; $P=0.02$) and

note publication on ClinicalTrials.gov (21.6% versus 9.6%; $P=0.04$). Black American–specific trials were more frequently a behavioral intervention (53.8% versus 22.7%; $P<0.01$) and publicly funded (34.6% versus 20.0%; $P=0.02$).

Our report indicates that the proportion of registered hypertension trials specific to Black American

adults remained unchanged over the study period. Trials specific to Black American adults were more likely to test behavioral interventions and receive public funding. Designing and testing interventions specific to the social context and lived experience of Black Americans may better inform how to address disparities in hypertension.

While there are many underrepresented populations with undue burden of hypertension, we chose to examine Black American adults specifically because of the healthcare context driven by systemic racism, contributing to chronically low access to healthcare resources available to many racial and ethnic groups, including Black Americans. Designing, testing, and implementing trial interventions specific for hypertension in the Black community, such as in BARBER-2 and FAITH, is a key strategy to reducing disparities in hypertension.^{3,4} The BARBER-2 and FAITH trials demonstrate novel approaches to improve hypertension treatment and control in Black American adults through delivering local decentralized health care by trusted members of the community in Black barbershops and churches.^{3,4} Clinical trials need to be designed to test behavioral, community, and policy interventions specifically for Black Americans.

Broadly, Black adults remain underrepresented in clinical trials, and as clinical trialists.² Entry into clinical trials can be prohibitive because of financial concerns, lack of access to centers performing trials, or mistrust and fear of exploitation.² Moreover, trialists' demographics may contribute to insufficient effort in design or recruitment, and lack of knowledge or care regarding opportunities to address health disparities in underrepresented communities. Greater funding of Black American investigators may help to improve design and conduct of trials addressing hypertension in Black communities.⁵

This study is limited by the use and accuracy of trialist-reported parameters on ClinicalTrials.gov. However, we believe our method enables a fair assessment of the clinical trial landscape.

There remain few registered hypertension trials specific to Black American adults. Greater awareness

by funding agencies and trial sponsors, with increased investment in clinical trials designed to test interventions that address and account for societal inequities and potentially varying antihypertensive responses specific to Black Americans, may help to address the additive risk of hypertension faced by Black Americans.

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REFERENCES

1. The SPRINT Research Group. A randomized trial of intensive versus standard blood-pressure control. *N Engl J Med*. 2015;373:2103–2116.
2. Oh SS, Galanter J, Thakur N, Pino-Yanes M, Barcelo N, White M, de Bruin D, Greenblatt R, Bibbins-Domingo K, Wu A, et al. Diversity in clinical and biomedical research: a promise yet to be fulfilled. *PLoS Med*. 2015;12:e1001918.
3. Schoenthaler A, Lancaster K, Chaplin W, Butler M, Forsyth J, Ogedegbe G. Cluster randomized clinical trial of faith (faith-based approaches in the treatment of hypertension) in blacks. *Circ Cardiovasc Qual Outcomes*. 2018;11:e004691. DOI: 10.1161/CIRCOUTCOMES.118.004691.
4. Victor RG, Lynch K, Li N, Blyler C, Muhammad E, Handler J, Brettley J, Rashid M, Hsu B, Foxx-Drew D, et al. A cluster-randomized trial of blood-pressure reduction in black barbershops. *N Engl J Med*. 2018;378:1291–1301.
5. Hoppe TA, Litovitz A, Willis KA, Meseroll R, Perkins M, Hutchins B, Davis A, Lauer M, Valentine H, Anderson J, et al. Topic choice contributes to the lower rate of NIH awards to African-American/Black scientists. *Sci Adv*. 2019;5:eaaw7238.