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Regional Variation in HIV Clinical Trials Participation in the United States

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Abstract

Objectives—To ensure generalizability of clinical research results, it is important to enroll a heterogeneous population that is representative of the target clinical population. Earlier studies have found regional variation in participation in human immunodeficiency virus (HIV) clinical trials, with the lowest rates seen in the southern United States. Rates of new HIV diagnoses are highest in the South, highlighting the need for in-depth understanding of disparities in clinical trial participation. We evaluated whether regional variation in study participation remains, and describe factors that facilitate or prevent HIV clinical trial participation by region.

Methods—A one-time, anonymous, bilingual, self-administered survey was conducted among HIV-infected adults receiving HIV care at all 47 domestic AIDS Clinical Trials Group clinical research sites, with a goal of completing 50 surveys per site. χ^2 tests were used to evaluate differences in knowledge of and participation in HIV clinical trials by region, including Northeast, Midwest, South, and West regions. Multivariable logistic regression was used to estimate odds ratios and 95% confidence intervals (CIs) for the effect of region on knowledge of and participation in HIV clinical trials.

Results—Of 2263 completed surveys, 2125 were included in this analysis. The proportion of respondents in the South who reported knowledge of studies (66%) was significantly lower than in the Northeast (76%), Midwest (77%), and West (73%) ($P = 0.001$). Respondents in the South also were the least likely group to report ever having tried to or having participated in a research study (51%) compared with respondents in the Northeast (60%), Midwest (57%), and West (69%; $P < 0.001$). After adjusting for age, sex, education, race/ethnicity, tobacco use, and alcohol use, the OR for knowledge of and participation in clinical trials for the Northeast (1.36; 95% CI 1.07–1.72) and West (1.85; 95% CI 1.39–2.45) remained significant compared with the South. African

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American respondents in the South were the most likely population group to report not understanding research studies (15%) as a reason for not participating, compared with the Northeast (9%), Midwest (8%), and West (6%; $P < 0.001$).

Conclusions—Significant regional variations in knowledge of and participation in HIV clinical trials exist. Our results suggest that increasing awareness and understanding of research studies, particularly among African Americans in the South, may facilitate HIV clinical trial participation that is more representative of the HIV-infected population across the United States.

Keywords

regional variation; HIV; research participation; clinical trials; United States

To ensure generalizability of clinical research results, it is important to enroll a heterogeneous population that is representative of the target clinical population. Women, racial/ethnic minorities, and those who have acquired the human immunodeficiency virus (HIV) by injection drug use are significantly underrepresented in HIV clinical trials in the United States.^{1–9} The HIV Cost and Service Utilization Study, a nationally representative sample of patients in care in the United States, using data from 1996 to 1998, found regional variation in the number of patients with HIV infection who had ever received experimental treatment, with the lowest participation noted in the South.⁴ Studies in the field of oncology also have revealed that the patients' place of residence has been shown to have a statistically significant effect on accrual to oncology clinical trials, with southern states, including Alabama, Arkansas, Florida, Georgia, Kentucky, and West Virginia, having the lowest accrual rates.¹⁰

The 2011 Centers for Disease Control and Prevention's HIV surveillance report shows regional variation in both the number of new HIV diagnoses and the total number of people living with HIV/acquired immunodeficiency syndrome (AIDS), with the highest rates of new HIV diagnoses now occurring in the South, followed by the Northeast, West, and Midwest in descending order.¹¹ Prevalence of AIDS was highest in the Northeast, followed by the South, West, and Midwest. There are no recent studies that have extensively evaluated how enrollment in HIV clinical trials varies by region.

This article describes regional variation in knowledge of and participation in HIV clinical trials among a population of patients receiving care at AIDS Clinical Trials Group (ACTG) clinical research sites. We used an anonymous, bilingual, self-administered survey to assess potential barriers to HIV clinical trial enrollment. Differences in knowledge of available research studies and attitudes and beliefs that facilitate or prevent enrollment were compared across regions to better understand reasons why certain groups enroll less often. The results of this study will help demonstrate where to target additional programs to enhance HIV clinical trial participation.

Methods

Survey Distribution and Content

The survey, developed by the Survey Working Group of the ACTG Underrepresented Populations Committee, was an anonymous, 7-page questionnaire written at a sixth-grade reading level, spanning 34 items in three categories: demographics, participation in clinical trials, and behaviors.

All 47 domestic ACTG clinical research sites were invited to participate in the survey and site participation was voluntary. All of the sites were sent 60 surveys in English and 12 in Spanish; however, the number of Spanish surveys could be increased upon site request. Sites were asked to distribute surveys, with a goal of completing 50 surveys per site. All ACTG sites participate in and offer patients access to clinical trials; however, patients cared for at these sites are not required to enroll in studies to receive routine HIV care at an ACTG site. HIV-infected individuals who were 18 years and older and attending the clinic site for regular medical care were approached for participation. Sites were encouraged to overrepresent women and minorities to allow for a diverse sample that would closely resemble the current demographics of the HIV epidemic in the United States. All of the sites obtained approval from their local institutional review board before initiating the study.

Respondents were given a paper copy of the survey and completed the survey confidentially. Respondents could receive assistance if they had problems reading the survey or if they had any questions regarding the survey. Once completed, the respondents placed the survey inside the provided envelope, sealed it, and gave it to the research nurse or coordinator. Sites were provided with preaddressed return shipping labels and were asked to return all completed surveys to the ACTG Data Management Center by completion of the enrollment period. Sites that did not adhere to this protocol were excluded from the analysis.

Statistical Analysis

χ^2 tests of independence were used to evaluate differences in responses to the survey questions by region. No adjustments were made for multiple comparisons. Regions were defined according to geographic definitions set forth in the Centers for Disease Control and Prevention's 2011 HIV surveillance report, as defined by the US Census Bureau¹¹: Northeast: Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont; Midwest: Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin; South: Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia; West: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming. Puerto Rico was not included in the analyses because it did not fit into one of the predefined geographic regions.

Logistic regression was used to estimate odds ratios (ORs) and 95% confidence intervals (CIs) for the effect of region on participation in HIV clinical trials (outcome variable) defined as having ever tried to participate or having ever participated in HIV clinical trials.

Univariate models evaluated the association of participation with region, race, education, age, sex, last use of tobacco, alcohol use, and marijuana and other drug use. Only variables that were significant at a univariate level with a $P \leq 0.2$ were included in the multivariable logistic regression model; sex was included in the multivariable model regardless of P value. All of the analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC).

Results

Demographics and Substance Abuse

A total of 3612 surveys were distributed to 47 sites and 2263 (63%) were returned. Five sites did not return any surveys. We included 2125 surveys in this analysis (88 were excluded from 2 sites because of protocol violations and 50 were excluded from the Puerto Rico site). The number of surveys completed by region was 682 (32%) from the Northeast, 498 (23%) from the Midwest, 516 (24%) from the South, and 429 (21%) from the West.

There were significant differences ($P < 0.001$) in age, race, sex, first language, and education levels in respondents among regions (Table 1). In the Midwest, more respondents were younger (younger than 34 years) and in the South, fewer respondents were older (older than 55 years). The survey was completed by fewer African Americans in the West (15%) and by fewer Hispanics in the Midwest (5%), as compared with other races and regions. The proportion of female respondents was highest in the Northeast (34%) and lowest in the West (15%). Only 2% reported Spanish as their first language in the Midwest, with other regions reporting 12% to 16%. Respondents in the West had higher overall levels of education, with 13% reporting graduate-level education, and respondents in the Northeast had lower levels of education, with 50% reporting a high school education or less (Table 1).

Recent (in the past month) use of alcohol differed by region, with the highest proportions in the West and the West reporting the most daily or nearly daily alcohol drinkers. The Midwest had the highest percentage of recent tobacco users (47%). Marijuana use (in the past year) was highest in the West and Midwest. Cocaine/heroin/amphetamine use (in the past year) and use of injected drugs were highest in the West and Northeast (Table 1).

Knowledge of and Participation in Studies

Respondents in the South reported that they had less awareness of HIV research studies compared with other regions, with only 66% reporting knowledge of studies (pairwise P values for the South compared with the Northeast and Midwest < 0.01 , pairwise P values for the South compared with the West = 0.1) and 60% having ever been talked to about research studies (all pairwise P values for the South < 0.01). Respondents in the South also were the least likely group to have ever thought about participating in a study (pairwise P values for the South compared with the Midwest and West < 0.05 , pairwise P values for the South compared with the Northeast = 0.2) and the least likely to have ever tried to participate in and to have ever participated in a research study (all pairwise P values for the South > 0.05 ; Table 2).

Facilitators/Barriers to Participation

When asked why one would want to participate in a study, more respondents in the Northeast reported wanting better representation of their sex in research studies (28%) compared with the West and the Midwest (both 22%) and the South (25%, $P=0.03$). Respondents in the Northeast (29%) and the South (28%) reported wanting better representation of their race in research studies compared with the Midwest or West (both 22%; $P < 0.006$). Respondents in the West (43%) were more likely to report that they would want to participate in a research study if their healthcare provider recommended it (Table 2).

When asked why one would not want to participate in a study, respondents in the Midwest (19%) and West (22%) expressed more concern about receiving a placebo compared with the Northeast (13%) and South (14%); in the Midwest (23%) and South (20%), they expressed concern that their information would not be kept secret. Respondents in the South (11%) were most likely to report that they did not understand research studies compared with the Northeast (8%), Midwest (7%) and the West (5%, $P=0.01$; Table 2).

Sex by Region

We included 2070 surveys in the analysis of sex by region (Table 3). Respondents who reported being transgender ($n = 13$) or did not report sex ($n = 44$) were not included in the analysis. When asked why one would want to participate in a study, 34% of females in the South and 38% of female respondents in the West reported that they wanted more of their race represented in studies compared with 30% in the Northeast and 20% in the Midwest. Furthermore, 34% of female respondents in the South and 52% of female respondents in the West reported they wanted more of their sex represented in studies compared with 29% in the Northeast and 23% in the Midwest. When asked why one would not want to participate in a study, across all regions male respondents were more worried about receiving a placebo than female respondents. Furthermore, male respondents in the Midwest (22%) and in the West (25%) were more worried about placebo than male participants in the Northeast (14%) or South (15%; Table 3).

Race by Region

We included 1947 surveys in this analysis stratified by race and region, because respondents who reported other ($n = 99$), mixed race ($n = 23$), or did not report race ($n = 56$) were not included in the analysis (Table 4). More Hispanics (21%) in the Midwest reported they would not want to participate in a study because studies are not “friendly” to people of their race compared with the Northeast (9%, $P = 0.06$), South (8%, $P = 0.08$), and West (10%, $P = 0.1$). Hispanics in the Midwest (38%) also were more worried that their information would be revealed compared with Hispanics in the Northeast (11%, $P = 0.001$), South (23%, $P = 0.2$), and West (20%, $P = 0.06$). Of note, the sample of Hispanics in the Midwest was small ($n = 24$). In the South, more African Americans (15%) reported they would not want to participate in a study because they do not understand studies as compared with 9%, 8%, and 6% in the Northeast, Midwest, and West, respectively (Table 4). The education of African Americans was not lower per se in the South, because 56% of African Americans in the Northeast, 42% in the Midwest, 47% in the South, and 29% in the West reported having a high school education or less. African Americans were more likely than Hispanics to report

that they wanted more of their race to be included in research studies in all regions except the South, where the high rates were comparable (Table 4).

First Language by Region

We included 1992 surveys in this analysis because respondents who did not report a first language ($n = 102$) or who reported speaking other languages ($n = 31$) were not included in the analysis. Respondents who reported Spanish as a first language in the South were more likely to want to participate in a study because a provider recommended (51%) it compared with 35% in the Northeast ($P = 0.04$), and 36% in the West ($P = 0.09$). Spanish speakers in the South also reported that they would not want to participate in studies because they worried about receiving a placebo (22%) compared with 7% in the Northeast ($P = 0.005$), and 17% in the West ($P = 0.5$; Table 5). In all regions except the South, more respondents who reported Spanish as a first language, as compared with those who reported English as a first language, said they would not want to participate in a study because they do not understand studies. In the South, nearly equal percentages of respondents who reported English (12%) and Spanish (11%) as a first language would not want to participate in a study because they do not understand studies (Table 5).

Effect of Region on Participation in HIV Clinical Trials

Fifty-nine percent of the respondents reported that they had tried to participate in or had participated in an HIV/AIDS research study (Table 2). After adjusting for age, sex, education, race/ethnicity, tobacco use, and alcohol use, the OR for ever having tried to participate in or ever having participated in an HIV/AIDS research study remained significantly higher for respondents in the Northeast (1.36; 95% CI 1.07–1.72) and West (1.85; 95% CI 1.39–2.45) compared with the South (Table 6); the OR for the Midwest compared to the South was no longer statistically significant ($P = 0.2$; Table 6).

We also evaluated the combined effect of sex and race in a multivariate model that included region, age, education, tobacco use, and alcohol use. Compared with white males, African American males and Hispanic males were less likely to report having tried to participate or having participated in a study with adjusted ORs of 0.74 (95% CI 0.57–0.95) and 0.59 (95% CI 0.43–0.81), respectively. The associations for white, African American, or Hispanic females were not statistically significant. The associations of region with having tried to participate or having participated in a study in this model with the combined effect of sex and race were consistent with those reported in Table 6.

Discussion

In this study, we demonstrated that there was regional variation in knowledge of and participation in HIV clinical trials among HIV-infected patients cared for at clinical sites where HIV clinical trials were being conducted. Our results show that respondents in the South were less likely to have ever tried to participate in a study, ever talked with a provider about participating in a study or participated in a study, and they had the least knowledge about studies. We also found that more respondents in the South reported that they would not want to participate in a study because they did not understand research studies, despite

reporting more than high school education levels that were similar to other regions, except the West, where a higher proportion had post-college educations. Respondents in the South, which had the highest proportion of African American respondents, were more likely to want to participate in HIV trials because they believed that more people of their race should be represented in research studies. After adjusting for age, sex, education, race/ethnicity, tobacco use, and alcohol use, there was no longer a statistically significant difference between the South and the Midwest in respondents reporting having tried to participate in or having ever participated in an HIV/AIDS research study.

Authors have described the similarities in the HIV epidemic among states in the Deep South and less wealthy nations in comparison with other areas of the United States, and have postulated contributing factors such as a high prevalence of poverty, reliance on public health programs, and residence in rural areas.¹² Studies investigating participation in cancer-related trials have found that racial and ethnic minorities, older adults, rural residents, and individuals of low socioeconomic status are underrepresented in trials, with the most reported barrier to participation being lack of awareness of clinical trials.¹³

We also found that African Americans in the South were more likely to report they would not want to participate in a study because they do not understand studies compared with African Americans in the other regions of the country. Parallel to this finding, nearly equal percentages of English and Spanish speakers in the South stated that they would not want to participate in a study because they do not understand HIV studies, which differed from the other regions in which only Spanish speakers were more likely to report not understanding studies as a barrier to participation.

A study investigating the attitudes and beliefs of African Americans toward participation in medical research found African Americans were concerned that they would be the least likely group to benefit from research.¹⁴ In addition, the analogy of “being used as a guinea pig” was not only extended to research but also included perceptions of care in a teaching medical facility.¹⁴ In a cross-sectional survey of African Americans in Durham, North Carolina and their willingness to participate in AIDS research in 1998, Sengupta et al found that distrust of research institutions was the strongest barrier to participation in AIDS clinical trials.¹⁵

We found that African Americans across the United States reported not wanting to be “used as a guinea pig” as a reason to not participate in studies. This finding also is supported by a smaller-scale study that showed that geographic region, sex, and socioeconomic status had no perceivable influence on respondent knowledge or feelings toward medical research or the Tuskegee Syphilis Study in particular.^{16,17} Multiple studies have found that provider beliefs about patients influence their behavior with patients, and medical providers who care for HIV-infected patients have reported that they assume that people of color are less interested in clinical trials, less likely to join trials, and are therefore less likely to refer them.^{18–20}

Our study had limitations. Our data were obtained from self-administered surveys, increasing the risk for reporting bias. Furthermore, the survey was distributed only to HIV-

infected patients at sites where clinical trials are being conducted and these sites were asked to overrepresent women and minorities. The surveys were not distributed randomly, so the differences in demographic characteristics do not represent the population characteristics of these regions as a whole. Although our sample may not have been representative of the general population of HIV-infected individuals receiving medical care, our respondents were cared for at sites where clinical trials are conducted and should theoretically be more likely to have knowledge of clinical trials. We still found significant discrepancies in knowledge and participation in HIV clinical trials across regions, however.

Comprehensive enrollment of a heterogeneous population in HIV/AIDS trials, including patients from various racial, social, and geographic backgrounds, is essential to ensure that the results can be applied and generalized to HIV-infected patients receiving care in the United States. The results of our study demonstrated regional variations in knowledge of and participation in HIV clinical trials and this information can be used to develop programs to educate patients and clinicians and to enhance clinical trial participation. Our results suggest that increasing awareness and understanding of research studies, particularly in the South among African Americans, may facilitate HIV clinical trial participation across the United States.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Key Points

- Patients in the southern United States infected with the human immunodeficiency virus were the least likely group to have ever tried to participate in or to have ever participated in a research study, ever talked with a provider about participating in a study, or have knowledge about ongoing studies.
- More respondents in the South reported that they would not want to participate in a study because they did not understand research studies, despite reporting education levels similar to other regions.
- African Americans in the South were more likely to report they would not want to participate in a study because they do not understand studies compared with African Americans in the other regions of the country.

Table 1

Demographics and substance abuse of survey participants by region

Characteristics	Total, N = 2125 (%)	Northeast, n = 682 (%)	Midwest, n = 498 (%)	South, n = 516 (%)	West, n = 429 (%)	<i>p</i> ^a
Age, y						
<34	368 (18)	82 (12)	135 (27)	86 (16)	65 (15)	<0.001
35–54	1356 (64)	454 (67)	283 (56)	347 (67)	272 (63)	
55	363 (17)	137 (20)	74 (15)	67 (13)	85 (20)	
Race						
White	675 (32)	172 (25)	186 (37)	114 (22)	203 (47)	<0.001
African American	871 (41)	286 (42)	255 (51)	266 (52)	64 (15)	
Hispanic	401 (19)	174 (26)	24 (5)	86 (17)	117 (27)	
Sex						
Male	1513 (71)	435 (64)	364 (73)	359 (70)	355 (83)	<0.001
Female	557 (26)	232 (34)	124 (25)	137 (27)	64 (15)	
First language						
English	1744 (82)	530 (78)	469 (94)	416 (81)	329 (77)	<0.001
Spanish	248 (12)	108 (16)	8 (2)	63 (12)	69 (16)	
Highest level of education						
High school or less	817 (38)	335 (50)	169 (34)	204 (39)	109 (25)	<0.001
Technical school or college	1090 (51)	285 (42)	289 (58)	261 (51)	255 (59)	
Graduate school (JD/PhD/MD/Masters)	164 (8)	44 (6)	34 (7)	32 (6)	54 (13)	
Drinks in past 30 d						
Never or 1/mo	1176 (55)	409 (60)	257 (52)	289 (56)	221 (52)	<0.001
2–3/mo or 1–2/wk	699 (33)	201 (30)	193 (39)	164 (32)	141 (33)	
Nearly daily/daily	146 (7)	39 (6)	25 (5)	35 (7)	47 (11)	
Tobacco use						
Never or >1 y ago	1074 (51)	328 (48)	235 (47)	258 (50)	253 (59)	<0.001
Within past year/past month	855 (40)	281 (41)	236 (47)	200 (39)	138 (32)	
Marijuana use						

Characteristics	Total, N = 2125 (%)	Northeast, n = 682 (%)	Midwest, n = 498 (%)	South, n = 516 (%)	West, n = 429 (%)	<i>p</i> ^a
Never or > 1 y ago	1342 (63)	422 (62)	314 (63)	357 (69)	249 (58)	<0.001
Within past year/past month	548 (26)	167 (24)	145 (29)	96 (19)	140 (33)	
Use of cocaine/heroin/amphetamines						
Never or > 1 y ago	1642 (77)	510 (75)	417 (84)	408 (79)	307 (72)	<0.001
Within past year/past month	256 (12)	89 (13)	44 (9)	44 (9)	79 (18)	
Ever injected or shot up drugs						
No	1640 (77)	506 (74)	425 (85)	399 (77)	310 (72)	<0.001
Yes	284 (13)	111 (16)	38 (8)	56 (11)	79 (18)	

Mixed race, transgender, other first language, and missing responses not shown in table.

^a χ^2 test of independence.

Table 2

Knowledge of and participation in HIV/AIDS research studies by region

Characteristics	Total, N = 2125 (%)	Northeast, n = 682 (%)	Midwest, n = 498 (%)	South, n = 516 (%)	West, n = 429 (%)	P ^{adj}
Know HIV/AIDS studies available to you?						
Yes	1398 (73)	468 (76)	344 (77)	299 (66)	287 (73)	0.001
No	314 (16)	102 (17)	57 (13)	93 (21)	62 (16)	
Not sure	199 (10)	47 (8)	46 (10)	60 (13)	46 (12)	
Thought about participating in a study?						
Yes	1555 (75)	492 (73)	370 (76)	346 (70)	347 (82)	<0.001
No	521 (25)	180 (27)	117 (24)	148 (30)	76 (18)	
Talked with you about research study?						
Yes	1435 (69)	453 (67)	371 (76)	299 (60)	312 (74)	<0.001
No	641 (31)	219 (33)	117 (24)	196 (40)	109 (26)	
Tried to participate in a research study?						
Yes	1167 (57)	384 (57)	266 (55)	239 (49)	278 (67)	<0.001
No	893 (43)	289 (43)	219 (45)	250 (51)	135 (33)	
Ever participated in a research study?						
Yes	983 (70)	304 (65)	237 (74)	204 (65)	238 (80)	<0.001
No	423 (30)	165 (35)	85 (26)	112 (35)	61 (20)	
Ever tried to participate or ever participated in a research study?						
Yes	1245 (59)	406 (60)	283 (57)	262 (51)	294 (69)	
No	880 (41)	276 (40)	215 (43)	254 (49)	135 (31)	
Facilitators to participation						
Help fight HIV/AIDS	1711 (81)	544 (80)	413 (83)	400 (78)	354 (83)	0.1
Could receive better care	798 (38)	245 (36)	182 (37)	198 (38)	173 (40)	0.5
Might get money	634 (30)	215 (32)	138 (28)	147 (28)	134 (31)	0.4
Help learn more	1129 (53)	352 (52)	271 (54)	275 (53)	231 (54)	0.8
Get unavailable meds	592 (28)	169 (25)	141 (28)	147 (28)	135 (31)	0.1
More of my sex represented	525 (25)	192 (28)	108 (22)	131 (25)	94 (22)	0.03

Characteristics	Total, N = 2125 (%)	Northeast, n = 682 (%)	Midwest, n = 498 (%)	South, n = 516 (%)	West, n = 429 (%)	P ^a
More of my race represented	548 (26)	197 (29)	110 (22)	147 (28)	94 (22)	0.006
Provider recommended	790 (37)	229 (34)	187 (38)	191 (37)	183 (43)	0.03
Friend/family in study	243 (11)	91 (13)	47 (9)	64 (12)	41 (10)	0.09
Other	88 (4)	29 (4)	18 (4)	21 (4)	20 (5)	0.9
Barriers to participation						
Not "friendly" to my race	232 (11)	71 (10)	64 (13)	55 (11)	42 (10)	0.4
Not "friendly" to my sex	164 (8)	53 (8)	40 (8)	42 (8)	29 (7)	0.9
Not "friendly" to drug user	171 (8)	54 (8)	40 (8)	44 (9)	33 (8)	0.9
Not "friendly" to alcohol user	139 (7)	42 (6)	34 (7)	39 (8)	24 (6)	0.6
Worry about being hurt	480 (23)	156 (23)	114 (23)	116 (22)	94 (22)	0.9
Worry about a placebo	348 (16)	90 (13)	93 (19)	70 (14)	95 (22)	<0.0001
Worry my information would be revealed	398 (19)	110 (16)	116 (23)	101 (20)	71 (17)	0.01
Worry about ineffective medications	666 (31)	199 (29)	169 (34)	165 (32)	133 (31)	0.4
Do not understand studies	170 (8)	54 (8)	35 (7)	58 (11)	23 (5)	0.01
Do not have time	325 (15)	103 (15)	75 (15)	76 (15)	71 (17)	0.9
Do not want to be "guinea pig"	243 (11)	79 (12)	57 (11)	69 (13)	38 (9)	0.2
Not involved because of religion	26 (1)	12 (2)	5 (1)	4 (1)	5 (1)	0.4

AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus.

^a χ^2 test of independence.

Table 3

Factors that influence HIV/AIDS clinical trial participation, stratified by region and sex

Characteristics	Total, N = 2070 (%) ^a	Northeast (%)		Midwest (%)		South (%)		West (%)		<i>P</i> ^b
		Male, n = 435	Female, n = 232	Male, n = 364	Female, n = 124	Male, n = 359	Female, n = 137	Male, n = 355	Female, n = 64	
Facilitators to participation										
More of my sex represented	517 (25)	121 (28)	67 (29)	79 (22)	28 (23)	82 (23)	47 (34)	60 (17)	33 (52)	<0.001
More of my race represented	539 (26)	123 (28)	69 (30)	84 (23)	25 (20)	98 (27)	47 (34)	69 (19)	24 (38)	0.001
Barriers to participation										
Worry about a placebo	343 (17)	62 (14)	25 (11)	81 (22)	12 (10)	55 (15)	14 (10)	90 (25)	4 (6)	<0.001

Only responses with statistically significant *P* values are included in table. AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus.

^a Respondents who reported transgender (n = 13) or did not report sex (n = 44) were not included in analysis.

^b *P* values from χ^2 test of independence.

Table 4

Factors that influence HIV/AIDS clinical trial participation, stratified by region and race

Characteristics	Total, N = 1947 ^a	Northeast (%)			Midwest (%)			South (%)			West (%)			P ^b
		W, n = 172	A, n = 286	H, n = 174	W, n = 186	A, n = 255	H, n = 24	W, n = 114	A, n = 266	H, n = 86	W, n = 203	A, n = 64	H, n = 117	
Facilitators to participation														
Help fight HIV/AIDS	1587 (82)	152 (88)	233 (81)	125 (72)	155 (83)	219 (86)	15 (63)	95 (83)	214 (80)	58 (67)	179 (88)	55 (86)	87 (74)	<0.001
Could receive better care	743 (38)	50 (29)	112 (39)	71 (41)	66 (35)	100 (39)	8 (33)	32 (28)	104 (39)	46 (53)	71 (35)	33 (52)	50 (43)	0.003
Help learn more	1053 (54)	92 (53)	168 (59)	72 (41)	103 (55)	143 (56)	10 (42)	51 (45)	157 (59)	48 (56)	101 (50)	41 (64)	67 (57)	0.004
Obtain unavailable medications	541 (28)	48 (28)	75 (26)	31 (18)	55 (30)	72 (28)	5 (21)	41 (36)	66 (25)	30 (35)	67 (33)	19 (30)	32 (27)	0.05
More of my sex represented	488 (25)	47 (27)	96 (34)	36 (21)	29 (16)	69 (27)	4 (17)	14 (12)	83 (31)	27 (31)	30 (15)	21 (33)	32 (27)	<0.001
More of my race represented	504 (26)	33 (19)	103 (36)	46 (26)	14 (8)	85 (33)	4 (17)	12 (11)	92 (35)	31 (36)	12 (6)	31 (48)	41 (35)	<0.001
Provider recommended	729 (37)	74 (43)	88 (31)	52 (30)	84 (45)	85 (33)	6 (25)	55 (48)	88 (33)	36 (42)	100 (49)	20 (31)	41 (35)	<0.001
Barriers to participation														
Not "friendly" to my race	213 (11)	5 (3)	45 (16)	15 (9)	7 (4)	47 (18)	5 (21)	5 (4)	40 (15)	7 (8)	10 (5)	15 (23)	12 (10)	<0.001
Not "friendly" to my sex	150 (8)	5 (3)	32 (11)	13 (7)	10 (5)	24 (9)	2 (8)	6 (5)	28 (11)	5 (6)	10 (5)	10 (16)	5 (4)	0.004
Not "friendly" to drug user	153 (8)	6 (3)	35 (12)	8 (5)	8 (4)	25 (10)	2 (8)	3 (3)	33 (12)	4 (5)	13 (6)	9 (14)	7 (6)	<0.001
Worry about a placebo	315 (16)	33 (19)	32 (11)	18 (10)	47 (25)	35 (14)	2 (8)	28 (25)	22 (8)	14 (16)	54 (27)	7 (11)	23 (20)	<0.001
Worry my info would be revealed	366 (19)	20 (12)	64 (22)	20 (11)	36 (19)	63 (25)	9 (38)	14 (12)	58 (22)	20 (23)	29 (14)	10 (16)	23 (20)	<0.001
Do not understand studies	156 (8)	5 (3)	26 (9)	18 (10)	10 (5)	20 (8)	3 (13)	6 (5)	41 (15)	8 (9)	5 (2)	4 (6)	10 (9)	<0.001
Do not want to be "guinea pig"	218 (11)	13 (8)	39 (14)	17 (10)	11 (6)	39 (15)	2 (8)	9 (8)	47 (18)	8 (9)	10 (5)	8 (13)	15 (13)	<0.001

Only responses with statistically significant P values included in table. A, African American; AIDS, acquired immunodeficiency syndrome; H, Hispanic; HIV, human immunodeficiency virus; W, white.

^a Respondents who reported other (n = 99), mixed race (n = 23), or did not report race (n = 56) were not included in analysis.

^b P values from χ^2 test of independence.

Table 5
Factors that influence HIV/AIDS clinical trial participation stratified by region and first language

Characteristic	Total, N = 1992 ^a	Northeast (%)		Midwest (%)		South (%)		West (%)		P ^b
		E, n = 530	S, n = 108	E, n = 469	S, n = 8	E, n = 416	S, n = 63	E, n = 329	S, n = 69	
Facilitators to participation										
Help fight HIV/AIDS	1629 (82)	437 (82)	73 (68)	401 (86)	3 (38)	341 (82)	41 (65)	280 (85)	53 (77)	<0.001
Could receive better care	756 (38)	180 (34)	48 (44)	175 (37)	1 (13)	151 (36)	37 (59)	124 (38)	40 (58)	<0.001
Might get money	612 (31)	184 (35)	22 (20)	135 (29)	1 (13)	133 (32)	10 (16)	108 (33)	19 (28)	0.01
More of my sex represented	508 (26)	154 (29)	27 (25)	107 (23)	1 (13)	106 (25)	24 (38)	67 (20)	22 (32)	0.02
More of my race represented	519 (26)	150 (28)	33 (31)	106 (23)	1 (13)	114 (27)	28 (44)	58 (18)	29 (42)	<0.001
Provider recommended	761 (38)	180 (34)	38 (35)	181 (39)	1 (13)	153 (37)	32 (51)	151 (46)	25 (36)	0.01
Barriers to participation										
Worry about a placebo	328 (16)	75 (14)	8 (7)	90 (19)	0 (0)	55 (13)	14 (22)	74 (22)	12 (17)	<0.001
Worry my information would be revealed	375 (19)	89 (17)	12 (11)	111 (24)	2 (25)	80 (19)	16 (25)	50 (15)	15 (22)	0.01
Do not understand studies	160 (8)	36 (7)	14 (13)	32 (7)	1 (13)	50 (12)	7 (11)	14 (4)	6 (9)	0.003

Only responses with statistically significant *P* values are included in table. AIDS, acquired immunodeficiency syndrome; E, English; HIV, human immunodeficiency virus; S, Spanish.

^a Respondents who did not report a first language (n = 102) or who reported other languages (n = 31) were not included in analysis.

^b *P* values from χ^2 test of independence.

Table 6

Odds ratios and 95% confidence intervals for the association of region with participation in HIV/AIDS research studies

Have you ever tried to participate in or have you ever participated in an HIV/AIDS research study? ^a	Unadjusted		Adjusted	
	OR (95% CI)	P	OR (95% CI)	P
Region				
South	Ref		Ref	
Northeast	1.43 (1.13–1.79)	0.003	1.36 (1.07–1.72)	0.01
Midwest	1.28 (0.99–1.63)	0.05	1.18 (0.91–1.52)	0.2
West	2.11 (1.62–2.75)	<0.0001	1.85 (1.39–2.45)	<0.0001
Race				
White	Ref		Ref	
African American	0.56 (0.45–0.69)	<0.0001	0.68 (0.54–0.85)	0.001
Hispanic	0.56 (0.43–0.72)	<0.0001	0.63 (0.47–0.83)	0.001
Education				
High school or less	Ref		Ref	
More than high school	1.45 (1.22–1.74)	<0.0001	1.27 (1.04–1.55)	0.02
Age categories, y				
<25	Ref		Ref	
25–34	1.48 (0.89–2.45)	0.1	1.42 (0.85–2.39)	0.2
35–44	1.68 (1.03–2.72)	0.04	1.62 (0.99–2.66)	0.06
45–54	2.09 (1.30–3.37)	0.002	1.99 (1.22–3.25)	0.006
55	2.71 (1.63–4.48)	0.0001	2.39 (1.43–4.02)	0.001
Sex				
Male	Ref		Ref	
Female	1.11 (0.91–1.35)	0.3	1.30 (1.05–1.61)	0.01
Last use of tobacco				
Never/>1 y ago	Ref		Ref	
Within past year or past month	0.86 (0.72–1.04)	0.1	0.93 (0.77–1.13)	0.5
Alcohol use				
Never or 1/mo	Ref		Ref	
>2–3 times/mo	1.11 (0.93–1.34)	0.2	1.14 (0.95–1.39)	0.2
Marijuana use				
Never/>1 y ago	Ref		—	
Within past month/year	1.12 (0.92–1.38)	0.3	—	—
Other drug use (cocaine, heroin, amphetamine)				
Never/>1 y ago	Ref		—	
Within past month/year	1.08 (0.83–1.42)	0.6	—	—

Based on the univariate analyses, variables with $P \leq 0.2$ were included in the adjusted model; sex was included in the model regardless of P value. Mixed race, transgender, and missing responses not shown in table (all $P > 0.05$). AIDS, acquired immunodeficiency syndrome; CI, confidence interval; HIV, human immunodeficiency virus; OR, odds ratio.

^aYes 1245, no 880. Odds ratios are for yes vs no.

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