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Research Article

Willingness, Attitudes, and Hesitancy Regarding Clinical Trial Participation Among Historically Marginalized Communities in Selected Florida Cities

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Abstract

Purpose: Racial and ethnic minorities remain underrepresented in U.S. clinical trials, limiting the generalizability of efficacy, safety, and pharmacokinetic findings. This study identified factors associated with attitudes, willingness, and hesitancy toward clinical-trial participation and examined their relationships with prior participation. **Materials and Methods:** Eight Florida A&M University College of Pharmacy community health ambassadors administered a survey to 675 adults in Florida from December 2022 through March 2023. Scale reliability was assessed using Cronbach's alpha. Chi-square tests, independent-samples t-tests, and multivariable linear and logistic regression analyses were conducted using SAS 9.4**. Results:** Participants were predominantly female (62%) and non-Hispanic Black (64%) and were recruited in Jacksonville (52.1%), Tallahassee (29.5%), and Tampa (18.4%). Only 36.2% had received clinical-trial education. Prior participation was more common among males than females (44.36% vs. 23.92%) and lowest among non-Hispanic Black participants (17.51%) compared with non-Hispanic White (63.04%), Hispanic (65.63%), and other racial groups (38.03%). After covariate adjustment, non-Hispanic Black participants and females were significantly less likely to report prior participation. Clinical-trial education was associated with greater willingness, more favorable attitudes, and less hesitancy. Prior participation was significantly associated with greater willingness (OR=3.71; 95% CI, 2.62–5.25), favorable attitudes (OR=1.58; 95% CI, 1.15–2.16), and lower hesitancy (OR=0.44; 95% CI, 0.29–0.67). **Discussion:** Persistent enrollment disparities among Black Americans and women may limit equitable access to novel therapies and the applicability of trial findings. Targeted education delivered by trusted community institutions and health professionals may improve willingness, reduce hesitancy, and promote more representative participation.

Keywords: Clinical trials; Participation in clinical trials; Willingness to participate; Attitude; Participation hesitancy; Racial and ethnic minorities

Introduction

Clinical trials are crucial for assessing the safety and efficacy of novel medical products. However, underrepresentation of racial and ethnic minorities in clinical trials remains a significant barrier to quality in development of novel vaccines and treatments and exacerbates health disparities [1-7]. For example, in a study on racial and ethnic inequities in oncology conducted between 2017 and 2022, clinical trial participation was significantly lower among Black patients (HR, 0.54; 95% CI, 0.36-0.81) and Latinx patients (HR, 0.46; 95% CI, 0.27-0.77) compared to white patients with metastatic pancreatic cancer [8].

Excluding racial and ethnic minority groups from clinical trials not only compromises the external validity of study findings but also prevents these populations from accessing investigational therapeutics and vaccines. Consequently, increasing diversity in clinical research has been prioritized by major healthcare agencies, including the National Institutes of Health [9-10]. The COVID-19 pandemic further underscored stark disparities in infection, hospitalization, and mortality across racial, ethnic, and socioeconomic lines, reigniting urgent calls to address underrepresentation in clinical trials [11].

Causes of low minority representation in clinical study enrollment are complex and multifaceted. Common barriers include fear of side effects [12], mistrust of the healthcare system [12-20], lack of trial-related knowledge [17,20], concerns regarding privacy and confidentiality [16], and inconvenience and costs [17,20,21]. Family encouragement has demonstrated lower odds of influencing non-Hispanic Blacks in their decision to participate in clinical trials relative to non-Hispanic Whites [21]. Furthermore, despite bearing a disproportionate disease burden, a recent study documented that non-Hispanic Black women continue to be inadequately represented in clinical research due to high participation costs, strained relationships with the medical and research community, and personal circumstances such as employment obligations, childcare and other routine responsibilities, transportation access, financial resources, insurance status, education, language, cultural background, health conditions, and available time. [22].

Using primary survey data, this study aimed to assess the effects of various participant characteristics, including demographic characteristics and prior receipt of education related to clinical trials, on participant attitudes towards clinical research, willingness to participate in clinical trials, and hesitancy to participate in clinical trials. The study also assessed associations between attitudes, willingness, and hesitancy and prior clinical trial participation. Results from this study will inform targeted intervention strategies to increase clinical research participation among racial and ethnic communities and promote equitable access to medical advances.

Materials and Methods

Data were collected by eight community health ambassadors affiliated with the Florida Agricultural and Mechanical University (FAMU) College of Pharmacy and Pharmaceutical Sciences, Institute of Public Health. To recruit the ambassadors, investigators identified community health advisors/ambassadors within each of the three targeted geographic areas: Jacksonville, Tallahassee, and Tampa, Florida.

Prior to data collection, the ambassadors participated in comprehensive educational and training sessions developed and led by a multi-disciplinary team of investigators, which comprised pharmacists, pharmaceutical scientists, student pharmacists, and other healthcare professionals. The training curriculum utilized investigator-developed educational materials covering the biology of SARS-CoV-2, COVID-19 infection pathology, vaccine mechanisms, the risks and benefits of COVID-19 clinical trial participation, the role of the pharmaceutical industry in clinical research, systemic barriers to clinical trial enrollment, and historical medical research mistrust.

Following training, the ambassadors utilized these standardized materials to facilitate four community-based educational sessions tailored to racial and ethnic minority groups within their respective geographic regions. To evaluate the impact of the intervention, community participants completed pre- and post-assessments measuring baseline knowledge and willingness to recruit patients to clinical trials, alongside evaluations of speaker effectiveness and learning objective achievement.

The baseline survey assessed sociodemographic characteristics (gender, age, race/ethnicity, level of education, and geographic location), as well as clinical research background and COVID-19-related experiences. Specifically, questions addressed whether the respondent had previously received education related to clinical research, had been asked to participate in a clinical trial, or had previously participated in a clinical trial. COVID-19 measures included prior infection history, loss of a close contact to COVID-19, vaccination status, and vaccine hesitancy (e.g., refusal or delay due to safety or efficacy concerns). Lastly, the survey evaluated whether the COVID-19 pandemic altered the respondents' opinions of clinical research or increased their desire to learn more about it. The research protocols were approved by the Florida A& M University Review Board.

Data Collection and Study Measures

Participant Recruitment and Study Eligibility

Data were collected by eight community health ambassadors. Participation in the study was voluntary, and surveys were administered either online or in person. Eligible participants included adults age ≥ 18 years who each identified as a member of a racial or ethnic minority group and resided in Jacksonville, Tallahassee, or Tampa Florida. Participant recruitment occurred between December 2022 and March 2023. A total of 776 participants were enrolled in the study, and data from 675 participants were included in the final analysis.

Definition of Variables

The following variables were assessed in this study:

- **Gender:** Categorized as male or female.
- **Age:** Categorized into five age brackets: 18-24, 25-34, 35-44, 45-54, and 55 years and older.
- **Race/ethnicity:** Categorized as Non-Hispanic White, Non-Hispanic Black, Hispanic, and Other.
- **Education:** Categorized into three levels: 1) Below high school, 2) High school complete or some college education (technical school, associate degree or bachelor's degree) and 3) Graduate-level education (including some graduate studies and completed graduate/professional degrees.
- **Prior Clinical Trial Education:** Dichotomized as yes or no based on whether the participant had previously received educational information regarding clinical trials.
- **Location:** Categorized by participant city of residence: Jacksonville, Tallahassee, and Tampa, Florida.

Construction of Scale Measures and Outcome Variables

A total of 23 items across three scales were used to measure willingness to participate, attitude towards clinical research, and vaccine/participation hesitancy.

1. Willingness to Participate: A 6-item scale measuring a participant's willingness to participate in clinical trials (Cronbach's α=0.88). Items included: (1) "If asked to participate in a clinical trial, I will consider participating," (2) "If asked to participate in a clinical trial of the COVID-19 vaccine, I will consider doing so", (3) "If a vaccine for a new strand of COVID-19 was available through a clinical trial, I would think about participating in the trial to get it", (4) "I would encourage family members or friends at high-risk of getting COVID-19 to participate in a COVID-19 vaccine clinical trial," (5) "My friends and family would support my decision to participate in a clinical trial," and (6) "My friends and family would support my decision to participate in a COVID-19 vaccine clinical trial."

2. Attitude Toward Clinical Research: A 6-item scale measuring a participant's attitude toward clinical research (Cronbach's α=0.82). Items included: (1) "Clinical research is necessary to move science forward," (2) "Clinical research helps the community where it is done," (3) "It is important for the general community to learn about clinical research," (4) "Participant safety is a priority in clinical research," (5) "Participant privacy is a priority in clinical research," and (6) "Ethics are prioritized in clinical research."

3. Vaccine/Participation Hesitancy: An 11-item scale measuring a participant's hesitancy toward clinical trial and vaccine participation (Cronbach's α=0.90). Items included: "My healthcare will worsen if I participate in a clinical trial," (2) "I am afraid of side effects I may experience in a clinical trial," (3) "I am afraid medicine would not work if given in a clinical trial," (4) "I am at higher risk of contracting COVID-19 than most others," (5) "Receiving the COVID-19 vaccine will increase my risk of a COVID-19 infection," (6) "I am afraid the COVID-19 vaccine would not work if given in a clinical trial," (7) "I worry the COVID-19 vaccine will cause a sickness like Parkinson's disease," (8) "I worry the COVID-19 vaccine will affect my chances of becoming pregnant," (9) "I worry COVID-19 was created by scientists to harm the general population," (10) "I worry I would concern my family if I participated in a clinical trial," and (11) "I am afraid of side effects I may experience in a COVID-19 vaccine clinical trial."

Scoring and Reliability: Response choices were based on a 5-point Likert scale ranging from 1 (Strongly disagree) to 5 (Strongly agree). Negatively worded items were reverse scored prior to analysis. Individual item scores were summed and averaged to calculate mean composite scale scores. Internal consistency reliability for each composite scale was assessed using Cronbach's alpha (α) and mean inter-item correlations.

4. Prior Clinical Trial Participation: A binary measure indicating whether the participant had ever participated in a clinical trial (1 = Yes, 0 = No).

Scale scores for willingness, attitude, and hesitancy were calculated as continuous mean composite scores derived from 5-point Likert-type items (1 = Strongly disagree to 5 = Strongly agree). Each of these three composite scales served a dual role in the statistical analyses: first, as continuous dependent outcomes in multiple linear regression models, and second, as primary independent predictors in multiple logistic regression models evaluating prior clinical trial participation.

Statistical Analysis

Descriptive statistics were used to summarize respondents' characteristics. A t-test for independent samples was used to compare mean scores for willingness, attitude, and hesitancy by whether respondents had ever participated in clinical trials. A chi-square test was used to investigate bivariate associations between categorical variables and prior participation in clinical trials. For outcome variables measured on a continuous scale, multiple linear regression models were used to assess factors associated with willingness, attitude, and hesitancy. For the binary outcome of ever having participated in clinical trials, Odds Ratios (ORs) and their Confidence Intervals (CIs) were estimated using a multiple logistic regression model. All analyses were performed using SAS (version 9.4), with a two-tailed p-value < 0.05 considered statistically significant.

Results

Table 1 presents the questions used to construct the willingness, attitude and hesitancy scales, along with the group's means and standard deviations stratified by clinical trial participation status. It also displays the mean differences between groups and corresponding p-values.

Scale Measures	Overall Mean and standard deviation	Ever Participated?		Mean Difference	P values
		No	Yes		
Willingness to participate[a]	3.54 (0.74)	3.32 ± 0.68	4.03 ±0.60	0.71	<.0001
Attitude towards clinical research[a]	3.99 (0.64)	4.04 ± 0.62	3.780 ± 0.73	0.15	0.004
Participation hesitancy[b]	2.93 (0.55)	2.93 ± 0.58	2.91 ± 0.47	0.06	0.366
[a]Response categories for these items are the following: 1= strongly disagree; 2= Disagree; 3=neutral; 4= agree; 5= strongly agree.					
[b]Response categories for these items are the following: 1= strongly agree; 2= agree; 3=neutral; 4= disagree; 5= strongly disagree.					

Table 1: Mean Scores and Standard Deviations of Willingness, Attitude, and Hesitancy Scales by Ever Participation in Clinical Trials.

Respondents who had participated in clinical trials demonstrated a significantly higher mean score for willingness than those who had never participated ($P < 0.0001$). The results also revealed a significant difference in attitude between the two groups, with prior participants exhibiting more favorable attitudes ($p=0.004$). In contrast, no statistically significant difference was observed in participation hesitancy between the two groups.

Reliability of the willingness, attitude, and hesitancy scales was calculated and is presented in Table 2. Cronbach's alpha (α), mean inter-item correlations, and range of the mean inter-item correlations were calculated to assess the internal reliability of the constructed measures. Each of the multi-item scales demonstrated high internal consistency, with Cronbach's alpha values ranging from 0.82 to 0.90. With respect to inter-item correlations, the average correlations fell within the acceptable range of 0.40-0.60 across all scales, demonstrating strong item redundancy and construct coherence.

	No. of Items	Cronbach alpha	Mean Inter-item Correlations	Range of Inter-item Correlations
Willingness to participate	6	0.88	0.547	0.42-0.63
Attitude towards clinical research	6	0.82	0.431	0.30-0.62
Participation hesitancy	11	0.90	0.422	0.25-0.65

Table 2: Reliability Measures of the Constructed Willingness, Attitude, Hesitancy Scales.

Table 3 presents the distribution of participant characteristics, the proportion with prior clinical trial participation across categories, and chi-square tests of bivariate association.

Characteristics	N (%)*	Percent Ever Participated	Chi-square statistic
Total	675 (100)	31.70	
Gender			
Female	418 (61.9)	23.92	30.69***
Male	257 (38.1)	44.36	
Age group			
18-24	104 (15.4)	31.73	45.11***
25-34	257 (38.0)	44.36	
35-44	137 (20.3)	29.20	
45-54	71 (10.5)	23.94	
55-64	63 (9.3)	14.29	
65 and above	44 (6.5)	4.55	
Race			
Non-Hispanic Blacks	434 (63.9)	17.51	130.33***
Non-Hispanic Whites	46 (6.8)	63.04	
Hispanics	128 (18.9)	65.63	
Other Race	71 (10.5)	38.03	
Education			
< HS, HS or Some College	258 (38.0)	27.52	3.57
College graduate, Technical or AA	218 (32.1)	34.86	
Graduate school or some GS	203 (29.9)	33.99	
Have you previously received education related to clinical trials?			
No	428 (63.8)	4.91	396.24***
Yes	243 (36.2)	79.42	
Location			
Jacksonville	354 (52.1)	27.40	92.12***
Tallahassee	200 (29.5)	55.50	
Tampa	125 (18.4)	6.40	

*Total may not sum to 675 for some of the questions because of missing data. ***P-value < 0.001

Table 3: Socio-demographic Characteristics of Study Participants by Ever Participation in a Clinical Trial.

Approximately 62% of participants were female, and 38% were male. The age distribution across categories was 15.4% (18-24 years), 38.0% (25-34 years), 20.3% (35-44 years), 10.5% (45-54 years), 9.3% (55-64 years), and 6.5% (65 years and older).

Nearly two-thirds of participants (63.9%) were non-Hispanic Black, followed by one-fifth Hispanic (18.9%), 6.8% were non-Hispanic White, and 10.5% other races; overall racial and ethnic minorities comprised 93% of the sample.

Thirty-eight percent of participants reported a high school education or less/some college; 32.1% had completed an associate degree, technical school, or college degree, and 29.9% had completed or attended graduate school.

Thirty-six percent of participants had previously received education related to clinical trials. Geographically, 52.1%, 29.5%, and 18.4% of respondents resided in Jacksonville, Tallahassee, and Tampa, respectively.

Overall, nearly one-third (31.7%) of respondents reported prior participation in a clinical trial. Except for education, all demographic and background variables demonstrated significant bivariate associations with prior participation. While 44.4% of males reported prior participation, only 23.9% of females reported prior participation. The percentage of respondents who reported prior participation in clinical trials decreased with age, indicating that younger respondents were more likely to have participated than older respondents.

Of racial/ethnic groups, the proportion of respondents who reported prior participation was lowest in non-Hispanic Black (17.5%) compared with non-Hispanic White (63.0%), Hispanic (65.6%), and other (38.0%). No statistically significant association was found between respondents' educational level and prior participation.

Previous receipt of education related to clinical trials was strongly associated with prior participation in clinical trials (79.4% among educated respondents vs 4.91% among uneducated respondents). Geographically, participation rates among respondents in Jacksonville, Tallahassee, and Tampa were 55.5%, 27.4%, and 6.4%, respectively.

Multivariate Analysis

Results from Multiple Linear Regression

Table 4 presents the results from multiple linear regression analysis predicting willingness, attitude, and hesitancy. Estimates of regression coefficients along with standard errors are reported. Only gender and prior clinical trial education were significantly associated with the willingness score. Specifically, females were less willing to participate in clinical trials compared with males (β= -0.197 p=0.056)). Conversely, respondents who previously received clinical trials' education expressed greater willingness to participate than those without prior education. Regarding participants' attitudes, prior clinical trial education had a significant positive impact on attitudes toward participating in clinical trials. Additionally, prior education significantly reduced hesitancy to participate. Overall, prior clinical trial education was consistently and strongly associated with higher willingness, more favorable attitude, and lower hesitancy toward clinical trial participation.

Variable	Willingness	Attitude	Hesitancy
Intercept	3.452 (0.148)**	3.922 (0.137)**	2.964 (0.138)**
Gender			
Male (Reference)			
Female	-0.197 (0.056)**	-0.037 (0.053)	0.048 (0.052)
Age			
18-24	0.039 (0.099)	-0.103 (0.093)	-0.055 (0.091)
25-34	0.086 (0.087)	-0.014 (0.082)	-0.140 (0.081)
35-44	-0.046 (0.091)	-0.024 (0.085)	-0.197 (0.083)*
45-54	-0.022 (0.106)	0.098 (0.099)	-0.107 (0.098)
55+ (Reference)			
Race			

Non-Hispanic Whites (Reference)			
Non-Hispanic Blacks	-.093 (0.116)	0.091 (0.112)	0.043 (0.110)
Hispanics	0.118 (0.121)	0.049 (0.126)	0.094 (0.114)
Other Race	-0.049 (0.137)	-0.112 (0.126)	0.089 (0.131)
Education			
< HS, HS or Some College (Reference)			
College graduate, Technical or AA	0.103 (0.066)	0.058 (0.062)	0.092 (0.058)
Graduate school or some GS	0142 (0.069)	0.030 (0.065)	0.161 (0.063)*
Received education related to clinical trials?			
No (Reference)			
Yes	0.391 (0.063)**	0.196 (0.059)**	-0.206 (0.059)**
Location			
Jacksonville (Reference)			
Tallahassee	0.105 (0.069)	-0.102 (0.064)	-0.084 (0.063)
Tampa	-0.128 (0.076)	-0.095 (0.071)	0.081 (0.068)
R-squared	0.220	0.041	0.085
*Significant at alpha < 0.05; **Significant at alpha < 0.01			

Table 4: Regression Estimates and Standard Errors of Factors Associated with Willingness, Attitude, and Hesitancy to Participate in Clinical Trials from Multiple Linear Regression Models.

Results from Logistic Regression

The results from multivariate logistic regression models are reported as odds ratios and 95% confidence intervals to estimate the likelihood of having participated in clinical trials. The binary dependent variable was defined as whether the respondent had ever participated in a clinical trial. (No = 0; Yes = 1).

Because the variable indicating prior clinical trial education was strongly and significantly associated with willingness, attitude, and hesitancy (as shown in Table 4), it was excluded to avoid multicollinearity. Similarly, the three continuous scales - willingness, attitude, and hesitancy to participate were correlated (correlation matrix not shown), hence we included only one of the scales in the logistic model to avoid multicollinearity.

The first column in Table 5 presents unadjusted Odds Ratios (uORs) and 95% CIs, followed by adjusted odds ratios from 4 models. Model 1 serves as the baseline model, incorporating socio-demographic variables and location. Model 2 adds willingness to Model 1; Model 3 adds attitude to the baseline model; and Model 4 adds hesitancy to the baseline model.

Variables	Unadjusted Odds Ratios	Adjusted Odds Ratios			
		Model 1	Model 2: Model 1 + Willingness	Model 3: Model 1 + Attitude	Model 4: Model 1 + Hesitancy
Sex: Male (Ref)	1.00	1.00	1.00	1.00	1.00
Female	0.39 (0.28-0.55)**	0.58 (0.39-0.87)**	0.69 (0.45-1.06)	0.58 (0.39-0.87)**	0.46 (0.29-0.76)**
Age					
18-24	3.80 (1.83-7.86)**	2.46 (1.06-5.74)**	1.61 (0.63-4.14)	2.46 (1.06-5.74)*	1.90 (0.63-5.71)
25-34	6.51 (3.40-12.45)**	2.10 (0.99-4.49)	1.65 (0.71-3.83)	2.10 (0.99-4.49)	1.85 (0.69-4.99)
35-44	3.37 (1.67-6.81)**	1.67 (0.75-3.72)	1.31 (0.53-3.23)	1.67 (0.75-3.72)	1.40 (0.48-4.07)
45-54	2.57 (1.14-5.78)**	1.77 (0.76-4.40)	1.99 (0.73-5.41)	1.76 (0.70-4.40)	1.86 (0.56-6.12)
55+ (Ref)	1.00	1.00	1.00	1.00	1.00
Race					
Non-Hispanic White (Ref)	1.00		1.00	1.00	1.00
Non-Hispanic Black	0.13 (0.07-0.24)**	0.22 (0.11-0.44)**	0.23 (0.11-0.50)**	0.22 (0.11-0.44)**	0.28 (0.12-0.67)**
Hispanics	1.12 (0.56-2.26)	1.33 (0.63-2.80)	1.31 (0.58-2.96)	1.33 (0.63-2.80)	2.23 (0.89-5.59)
Other Races	0.36 (0.17-0.77)**	0.63 (0.27-1.46)	0.63 (0.25-1.57)	0.63 (0.27-1.46)	0.84 (0.29-2.43)
Education					
< HS, HS or Some College (Ref)	1.00	1.00	1.00	1.00	1.00
College grad, Technical or AA	1.41 (0.95-2.08)	1.20 (0.74-1.97)	0.99 (0.58-1.72)	1.20 (0.74-1.97)	1.51 (0.83-2.75)
Graduate school or some GS	1.36 (0.91-2.02)	0.99 (0.59-1.65)	0.84 (0.48-1.47)	0.99 (0.59-1.65)	1.17 (0.62-2.21)
Location					
Jacksonville (Ref)	1.00	1.00	1.00	1.00	1.00
Tallahassee	3.30 (2.30-4.75)**	1.75 (1.13-2.73)**	1.51 (0.93-2.44)	1.75 (1.13-2.73)**	2.05 (1.19-3.52)**
Tampa	0.18 (0.09-0.39)**	0.26 (0.11-0.57)**	0.29 (0.12-0.70)**	0.26 (0.11-0.57)**	0.16 (0.05-0.50)**
Scales					
Willingness	5.08 (3.70-6.98)**		3.71 (2.62-5.25)**		
Attitude	1.48 (1.13-1.93)**			1.58 (1.16-2.16)**	
Hesitancy	0.36 (0.25-0.52)**				0.44 (0.29-0.67)**
Log-Likelihood Ratio		461.36**	241.88**	190.97**	192.83**
*Significant at alpha < 0.05; **Significant at alpha < 0.01					

Table 5: Odds Ratios and 95% Confidence Intervals from Multiple Logistic Regression Models Estimating the Effects of Willingness, Attitude, and Hesitancy on Ever Having Participated in Clinical Trials.

The unadjusted odds ratios indicate that all included characteristics, except for educational level, were significantly associated with prior participation in clinical trials. The results are also consistent with the results presented in Table 3.

In the bivariate or unadjusted associations (Model 1), the odds of clinical trial participation were 61% lower among females than males (uOR= 0.39, 95% CI: 0.28-0.55). Similarly, non-Hispanic Black respondents had 87% lower odds of prior clinical trial participation relative to non-Hispanic Whites (aOR= 0.13, 95% CI: 0.07-0.24). In Model 1, gender, age, race/ethnicity, and location were associated with prior participation in clinical trials. After adjusting for the effects of other variables in the model, non-Hispanic Blacks were significantly less likely to have ever participated in clinical trials than non-Hispanic Whites (aOR = 0.22, 95% CI: 0.11-0.44). Regarding location, respondents from Tallahassee were more likely to have participated in clinical trials compared with those from Jacksonville (aOR = 1.75 95% CI: (1.13-2.73), whereas Tampa residents were less likely to have ever participated (aOR = 0.26 95% CI: (0.11-0.57). Subsequent models incorporated the attitudinal scales. Model 2 demonstrated that higher willingness was positively associated with prior participation in clinical trials (aOR = 3.71, 95% CI: 2.62-5.15). Model 3 revealed that a more positive attitude toward clinical research significantly increased the likelihood of having participated in clinical research (aOR = 1.58, 95% CI: 1.15-2.16). Finally, Model 4 also indicated that greater participation hesitancy was associated with decreased participation in clinical trials (aOR = 0.44, 95% CI: 0.29-0.67).

Discussion

Our study provides important insights into the persistently low participation rates of African Americans and women in clinical trials. Specifically, our analysis shows that non-Hispanic Black respondents demonstrated significantly lower odds of prior participation relative to non-Hispanic White or Hispanic respondents. Females were also approximately 60% less likely to have participated in clinical trials than males. Most importantly, our findings demonstrate that prior clinical trial education plays a vital, consistent role in improving engagement: it significantly increases willingness, fosters more favorable attitudes, and mitigates hesitancy to participate.

Achieving representation in clinical research is essential to ensure that trial findings are generalizable and that populations most impacted by disease can access novel therapeutics and vaccines. Some diseases affect racial and ethnic groups disproportionately, as evidenced by the severe racial disparities in morbidity and mortality observed during the COVID-19 pandemic. Consequently, developing clear, current, and culturally sensitive educational curricula—delivered by trusted community institutions and healthcare professionals—represents an actionable strategy to dismantle participation barriers, build trust, and advance health equity. This study demonstrates that the attitudes, perceptions, fears, and distrust in the healthcare system and pharmaceutical industry among African Americans, which arise from past research misconducts, including the legacy of the U.S. Public Health Service Tuskegee Syphilis Study 23, can be improved through clinical research education.

The study has several strengths, including utilization of trained community health ambassadors for data collection, extensive collaboration with community healthcare providers, a relatively large sample size of minority participants, reliable scale measures, and robust data analysis. A limitation of the study is reliance on a convenience sample, which limits the generalizability of the findings to the larger population. A further limitation is reliance on respondent self-reports to provide an accurate representation of their desires, perceptions, fears, distrust, attitudes, behavior, and/or circumstances.

Conclusion

In conclusion, our study underscores crucial contexts and factors that contribute to participation in clinical trials. Results of this study suggest that provision of training and educational opportunities related to clinical trials may enhance clinical trial recruitment, underscoring the importance of developing targeted interventional strategies to improve the engagement of minority individuals. Working with community health ambassadors that have a strong understanding of the history and legacy of past research misconduct, as well as and social perspectives of those likely to participate in future clinical trials, can enhance recruitment across racial and ethnic minority groups and advance equitable representation in and benefit from clinical research.

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