PATIENT ACTIVATION AND CLINICAL TRIAL PARTICIPATION IN A RACIALLY/ETHNICALLY DIVERSE POPULATION WITH INFLAMMATORY BOWEL DISEASE: RESULTS FROM THE NATIONAL HEALTH AND WELLNESS SURVEY

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INTRODUCTION

- The Patient Activation Measure (PAM) is a validated instrument that assesses a patient's knowledge, skills, beliefs, and confidence for managing health and heath care.[1] Patients with low PAM scores are typically passive recipients of care, whereas those with high scores are highly engaged and active in their health.[2]
- There are known differences in patient activation between White and Black individuals; however, limited research has examined differences across other racial/ethnic groups.[3-6]
- A patient's engagement in their health care may also influence clinical trial participation.
- Black, Indigenous, and People of Color (BIPOC) are often underrepresented in clinical trials[7-9], including in clinical trials of inflammatory bowel disease (IBD) therapies[10], limiting the generalizability of study results. However, recent findings in colon cancer research have shown BIPOC enrollment rates are similar to those of White participants when the BIPOC participants are offered the opportunity to partake in culturally sensitive settings that address social determinants of health-related barriers.[9]
- The objective was to evaluate the relationship between race/ethnicity, PAM scores, and clinical trial participation in participants with IBD.

METHODS

- Data were obtained from the 2018, 2019, and 2020 US National Health and Wellness Survey (NHWS), a self-administered, internet-based questionnaire collected from a nationwide sample of adults in the general population that includes approximately 75,000 participants per year.[11]
- Inclusion criteria were as follows:
  - ≥18 years and a US resident at the time of study
  - Self reported Hispanic ethnicity or White or Black race and self-reported physician diagnosis of Crohn's disease (CD) or ulcerative colitis (UC)
  - Valid PAM score
- Patient activation was assessed using the validated PAM measure in which 13 items are rated by the participant on a 4-point scale (1: strongly disagree to 4: strongly agree); raw scores were converted to a total PAM score (0–100) and categorized into an activation level (1–4).
- Clinical trial participation was measured using the NHWS survey question: "Have you ever participated in a clinical trial?"
- Bivariate analyses were conducted to compare study variables across racial/ethnic groups.
- Analyses were conducted separately for the CD and UC cohorts using Chi-square tests, analysis of variance (ANOVA), and independent sample t tests.
- Multiplicity adjustments were conducted using the Bonferroni correction for multiple comparisons.

CONCLUSIONS

- Despite reporting significantly lower mean PAM scores than White participants, a significantly higher proportion of Black and Hispanic participants with self-reported CD and UC reported previous participation in a clinical trial.
- Although these findings are surprising given the intuitive associations between patient activation and clinical trial participation, it is possible that the study participants had exposure to more culturally sensitive settings for clinical trial participation, or that the association between PAM and clinical trial participation is more tenuous than prior research reports.
- The findings of this study highlight important differences in sociodemographics, patient activation, and clinical trial participation across Black, Hispanic, and White individuals with IBD.
- Further research is needed to better understand the factors influencing clinical trial participation among BIPOC individuals as well as the direct relationship between PAM scores and clinical trial participation across racial/ethnic groups to further elucidate these findings.

RESULTS

Sociodemographic Characteristics

- Analyses included a total of 2,577 participants:
  - CD: 818 White (76.0%), 109 Black (10.1%), and 150 Hispanic (13.9%)
  - UC: 1,150 White (76.7%), 99 Black (6.6%), and 251 Hispanic (16.7%)
- Several sociodemographic characteristics differed significantly ($P < 0.05$) between racial/ethnic groups (Table 1).
  - Mean age was lower among Black and Hispanic participants with CD and UC than among White participants (all $P < 0.001$).
  - A greater proportion of Hispanic participants with CD and UC were employed full time than White participants (both $P < 0.001$).
  - A greater proportion of Black participants with CD had a household income <$25,000 USD than White ($P < 0.001$) and Hispanic ($P = 0.001$) participants.
  - A greater proportion of Black and Hispanic participants with CD did not have commercial health insurance than White participants (both $P = 0.02$); similarly, more Hispanic participants with UC lacked health insurance than White participants ($P = 0.001$).
  - Severe disease was more frequently reported among Black participants with CD than among White participants ($P = 0.03$) and among Hispanic participants with UC than among White participants ($P = 0.04$).

Table 1. Sociodemographic characteristics

	Crohn's Disease (N = 1,077)			Ulcerative Colitis (N = 1,500)		
	White (n = 818)	Black (n = 109)	Hispanic (n = 150)	White (n = 1,150)	Black (n = 99)	Hispanic (n = 251)
Female, n (%)	421 (51.5%)	55 (50.5%)	55 (36.7%)[†]	696 (60.5%)	47 (47.5%)[*]	138 (55.0%)
Age in years, mean (SD)	48.34 (16.48)	36.84 (14.39)[*]	34.05 (11.05)[†]	52.48 (16.28)	38.48 (16.08)[*]	38.45 (14.27)[†]
Marital status, n (%)						
Married/living with partner	518 (63.3%)	37 (33.9%)[*]	94 (62.7%)[‡]	718 (62.4%)	29 (29.3%)[*]	125 (49.8%)[†‡]
Single, not married/divorced/separated/widowed	299 (36.6%)	71 (65.1%)[*]	56 (37.3%)[‡]	429 (37.3%)	70 (70.7%)[*]	124 (49.4%)[†‡]
Decline to answer	1 (0.1%)	1 (0.9%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	2 (0.8%)
Education, n (%)						
Less than a college graduate	383 (46.8%)	66 (60.6%)[*]	81 (54.0%)[†]	564 (49.0%)	59 (59.6%)	133 (53.0%)
College graduate or higher	434 (53.1%)	43 (39.4%)[*]	69 (46.0%)[†]	582 (50.6%)	39 (39.4%)	118 (47.0%)
Decline to answer	1 (0.1%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	1 (1.0%)	0 (0.0%)
Employment status, n (%)						
Employed full time	364 (44.5%)	56 (51.4%)	94 (62.7%)[†]	424 (36.9%)	44 (44.4%)	132 (52.6%)[†]
Self-employed	54 (6.6%)	9 (8.3%)	13 (8.7%)	78 (6.8%)	9 (9.1%)	15 (6.0%)
Employed part time	83 (10.1%)	14 (12.8%)	12 (8.0%)	85 (7.4%)	17 (17.2%)[*]	30 (12.0%)
Homemaker	39 (4.8%)	7 (6.4%)	3 (2.0%)	73 (6.3%)	3 (3.0%)	19 (7.6%)
Retired	159 (19.4%)	2 (1.8%)[*]	9 (6.0%)[†]	321 (27.9%)	9 (9.1%)[*]	29 (11.6%)[†]
Student	21 (2.6%)	9 (8.3%)[*]	7 (4.7%)	16 (1.4%)	8 (8.1%)[*]	8 (3.2%)
Long-term disability	56 (6.8%)	5 (4.6%)	5 (3.3%)	84 (7.3%)	2 (2.0%)	12 (4.8%)
Not employed (whether looking for work or not)	42 (5.1%)	7 (6.4%)	7 (4.7%)	69 (6.0%)	7 (7.1%)	6 (2.4%)
Household income, n (%)						
<$25,000	102 (12.5%)	32 (29.4%)[*]	16 (10.7%)[‡]	166 (14.4%)	22 (22.2%)	39 (15.5%)
$25,000 to <$50,000	163 (19.9%)	20 (18.3%)	29 (19.3%)	235 (20.4%)	25 (25.3%)	53 (21.1%)
$50,000 to <$100,000	289 (35.3%)	29 (26.6%)	47 (31.3%)	409 (35.6%)	29 (29.3%)	74 (29.5%)
$100,000+	246 (30.1%)	27 (24.8%)	57 (38.0%)	299 (26.0%)	23 (23.2%)	77 (30.7%)
Decline to answer	18 (2.2%)	1 (0.9%)	1 (0.7%)	41 (3.6%)	0 (0.0%)	8 (3.2%)
Health insurance, n (%)						
Not insured	58 (7.1%)	16 (14.7%)[*]	21 (14.0%)[†]	88 (7.7%)	11 (11.1%)	37 (14.7%)[†]
Commercially insured	456 (55.7%)	65 (59.6%)	91 (60.7%)	583 (50.7%)	54 (54.5%)	149 (59.4%)[†]
Medicaid	81 (9.9%)	10 (9.2%)	11 (7.3%)	85 (7.4%)	13 (13.1%)	21 (8.4%)
Medicare	203 (24.8%)	15 (13.8%)[*]	14 (9.3%)[†]	362 (31.5%)	16 (16.2%)[*]	27 (10.8%)[†]
Other type of insurance/unsure	20 (2.4%)	3 (2.8%)	13 (8.7%)[†]	32 (2.8%)	5 (5.1%)	17 (6.8%)[†]
Severity of condition, n (%)						
Mild	514 (62.8%)	51 (46.8%)[*]	83 (55.3%)	789 (68.6%)	61 (61.6%)	134 (53.4%)[†]
Moderate	249 (30.4%)	43 (39.4%)	50 (33.3%)	300 (26.1%)	27 (27.3%)	93 (37.1%)[†]
Severe	55 (6.7%)	15 (13.8%)[*]	17 (11.3%)	61 (5.3%)	11 (11.1%)	24 (9.6%)[†]

[*]$P < 0.05$ between Black and White participants. [†]$P < 0.05$ between Hispanic and White participants. [‡]$P < 0.05$ between Hispanic and Black participants.
Abbreviations: SD = standard deviation.

Patient Activation Measure Scores

- Mean PAM scores were significantly lower in Black and Hispanic participants with CD and UC than in White participants (Figure 1).

Figure 1. Mean Patient Activation Measure score[a] in participants with self-reported inflammatory bowel disease
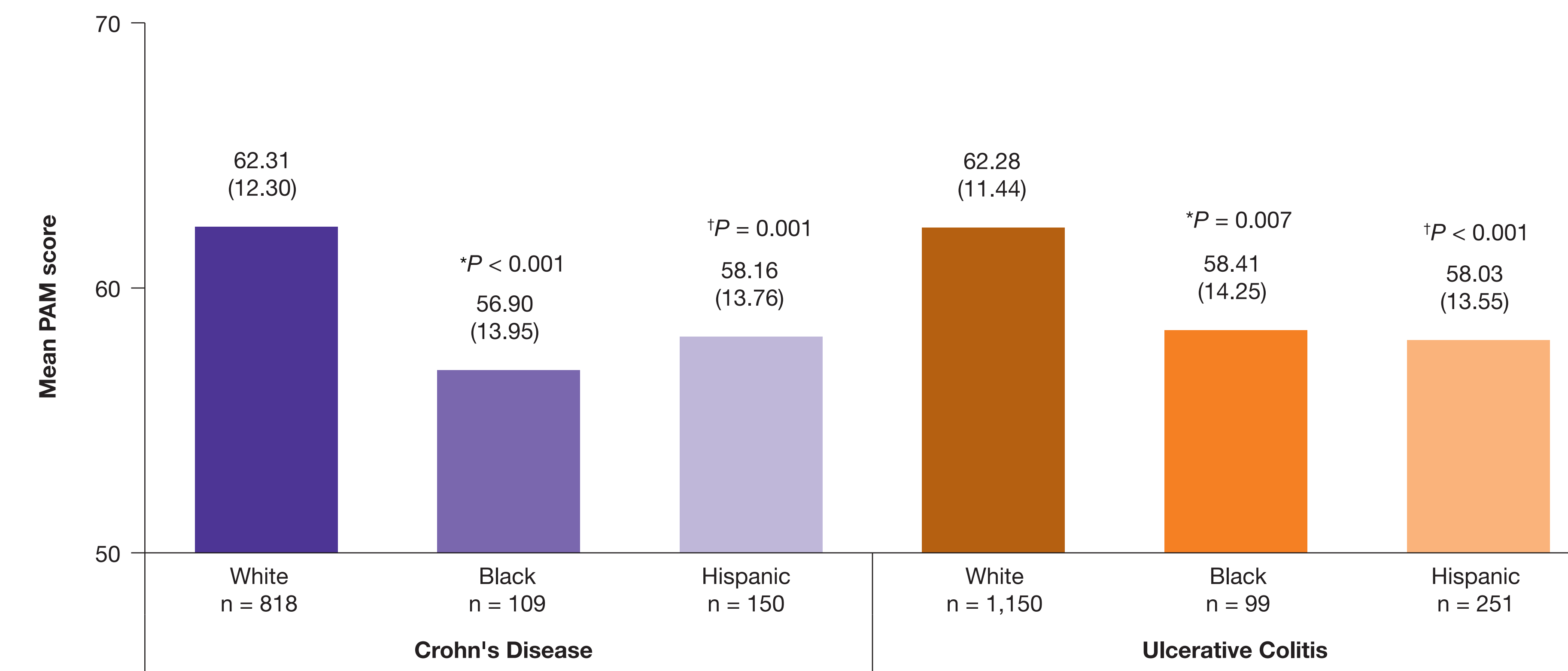
Values are presented as mean PAM score (standard deviation).
[a]PAM scores range from 0 to 100 where higher scores indicate higher levels of activation.
[*]$P < 0.05$ between Black and White participants. [†]$P < 0.05$ between Hispanic and White participants.
Abbreviations: PAM = Patient Activation Measure.

- Compared with White participants with CD, a significantly higher percentage of Hispanic participants with CD reported a PAM Level score of 1 (i.e., disengaged and overwhelmed) and a significantly lower percentage of Hispanic participants reported a PAM Level score of 3 (i.e., taking action; Table 2).
- Compared with White participants with UC, significantly higher percentages of Black and Hispanic participants with UC reported a PAM Level score of 1, and significantly lower percentages of Black and Hispanic participants with UC reported a PAM Level score of 3 (Table 2).

#### Table 2. PAM Level in White, Black, and Hispanic participants with self-reported inflammatory bowel disease

	Crohn's Disease (N = 1,077)			Ulcerative Colitis (N = 1,500)		
	White (n = 818)	Black (n = 109)	Hispanic (n = 150)	White (n = 1,150)	Black (n = 99)	Hispanic (n = 251)
PAM Level, n (%)						
Level 1 – Disengaged and overwhelmed	70 (8.6)	17 (15.6)	35 (23.3)[†]	84 (7.6)	25 (25.3)[*]	56 (22.3)[†]
Level 2 – Becoming aware, but still struggling	134 (16.4)	28 (25.7)	29 (19.3)	202 (17.6)	19 (19.2)	45 (17.9)
Level 3 – Taking action	475 (55.9)	50 (45.9)	64 (42.7)[†]	656 (57.0)	39 (39.4)[*]	114 (45.4)[†]
Level 4 – Maintaining behavior and pushing further	157 (19.2)	14 (12.8)	22 (14.7)	205 (17.8)	16 (16.2)	36 (14.3)

[a]PAM scores range from 0 to 100 where higher scores indicate higher levels of activation; scores correlate to one of four levels of patient activation. [*]$P < 0.05$ between Black and White participants. [†]$P < 0.05$ between Hispanic and White participants. [‡]$P < 0.05$ between Hispanic and Black participants.
Note. P values were calculated using Bonferroni-adjusted pairwise comparisons.
Abbreviations: PAM = Patient Activation Measure; SD = standard deviation.

Clinical Trial Participation

- A significantly greater proportion of Black and Hispanic participants with CD and UC reported previous clinical trial participation than White participants (Figure 2).

Figure 2. Mean Patient Activation Measure score[a] in participants with self-reported inflammatory bowel disease
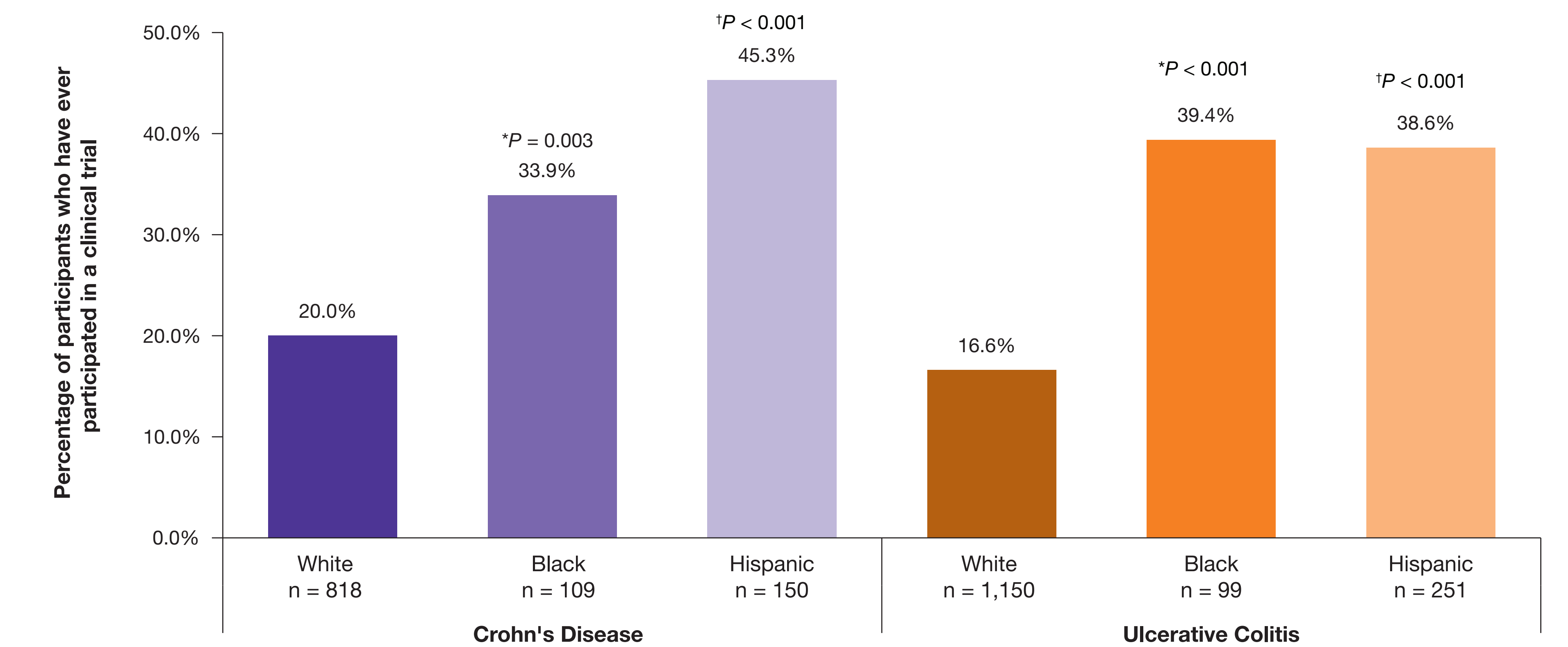
[*]$P < 0.05$ between Black and White participants. [†]$P < 0.05$ between Hispanic and White participants.

Limitations

- Limitations include the use of convenience sampling (as respondents self-select to participate in the NHWS which may underrepresent some groups and differ from the broader US population), relatively small sample sizes for the Black and Hispanic groups, the self-reported nature of the data, potential misinterpretation of the study question, participation in clinical trials not related to IBD, and use of only bivariate statistics.

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