

Racial/Ethnic Group Differences in Response Rate to a Mail Invitation to Participate in a Lifestyle Intervention Trial to Prevent Cognitive Decline (U.S. POINTER Trial)



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Introduction

- A recent systematic review of ethnoracial diversity in Alzheimer's disease (AD) clinical trials from 2001-2019 found that 95% of participants were White¹
- The Alzheimer's Association and National Institutes of Health have set a high priority on increasing diversity in AD clinical trials²
- The U.S. Study to Protect Brain Health through Lifestyle Intervention to Reduce Risk (U.S. POINTER) trial, sponsored by the Alzheimer's Association, established a recruitment target of 23% representation of racial/ethnic minority groups
- Baylor College of Medicine Department of Neurology, in partnership with the Kelsey Research Foundation (KRF), in Houston, Texas, is one of five sites implementing the U.S. POINTER trial
- Houston metro area: 33% White, 17% Black, 8% Asian, 39% Hispanic
- The principal recruitment source for the Houston site is the primary care patient populations of Baylor and KRF

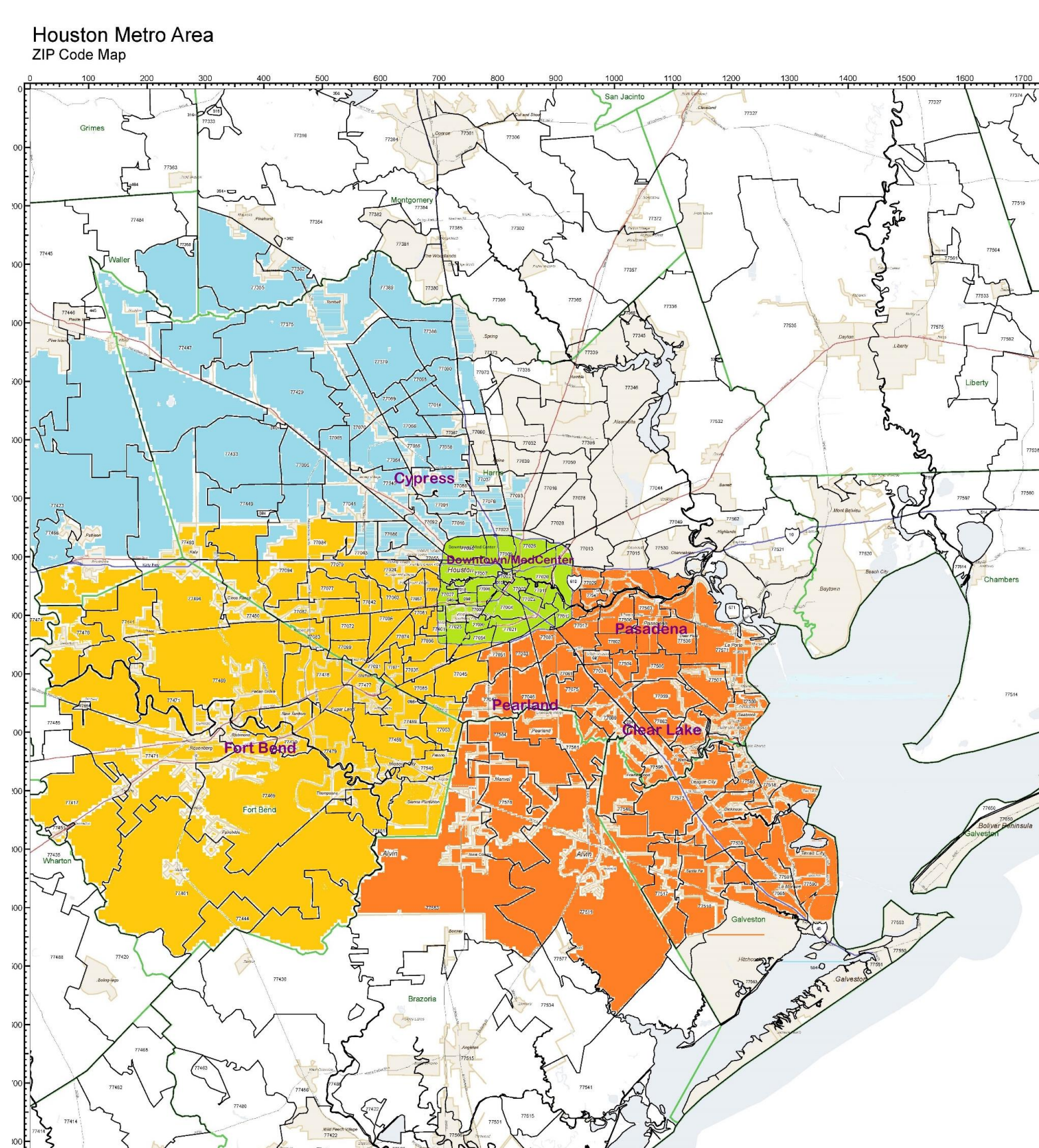


Figure 1. Recruitment Target Areas

Objective

To determine whether there were significant racial/ethnic group differences in response rates to a mailed recruitment letter inviting participation in a multi-modal lifestyle intervention, the U.S. POINTER trial, to prevent cognitive impairment in older individuals with a high cardiovascular risk factor burden

Methods and Materials

- Baylor and KRF used their electronic medical records (EMR) to identify potentially eligible participants based on age and medical history
- Participants were mailed a recruitment letter with instructions to access an online application to begin the screening process
- For logistical reasons, recruitment was conducted in waves corresponding to the neighborhoods in which patients resided.
- Five "neighborhoods" were defined based on distinct urban and suburban ZIP code areas within the Houston metro area (see **Figure 1**)
- "Response" was defined as an individual having accessed the U.S. POINTER application system to provide preliminary screening information
- Response rates across racial/ethnic groups within neighborhood were compared using descriptive statistics
- The independent role of racial/ethnic group classification in the overall likelihood of responding to the recruitment letter was evaluated in a logistic regression model controlling for age, sex, and neighborhood
- Analysis was limited to patients with complete demographic information (age, race, ethnicity, sex) in the EMR

Results

- 76,163 of 81,302 (93.9%) letter recipients included in the analysis
 - Most common missing variable was race/ethnicity
- Racial/ethnic distribution of letter recipients was 45% non-Hispanic white (NHW), 25.2% Black/African American (AA), 16.6% Hispanic, 12.9% other (**Figure 2**)
- Overall, 1.6% of letter recipients responded, and response rates varied across racial/ethnic groups (**Figure 3**)
- Overall, 36.4% of responses were from racial/ethnic minority groups (Figure 4)
- In logistic regression analysis, all demographic variables were independently and significantly associated with response rate (**Table 1**)

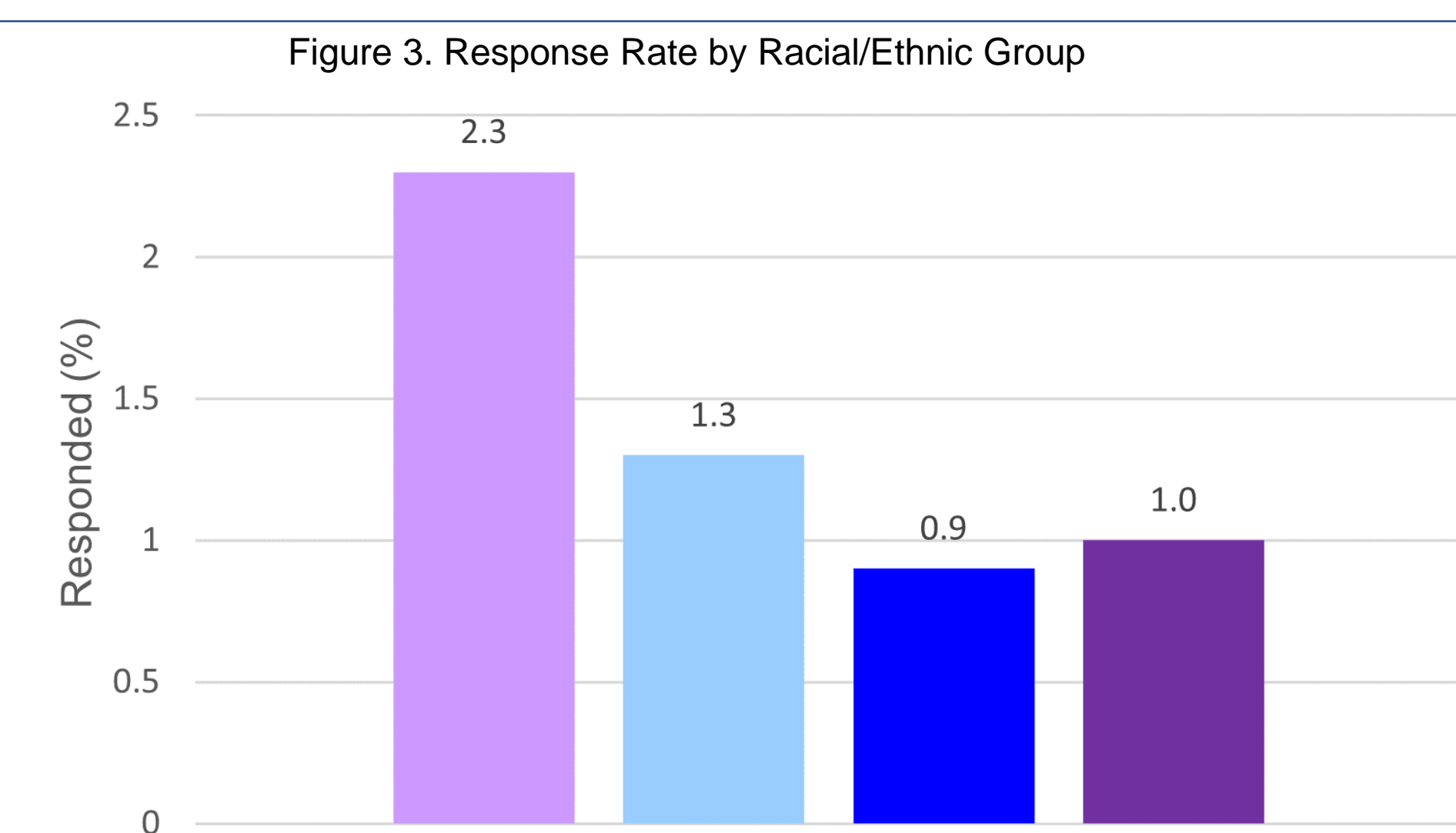
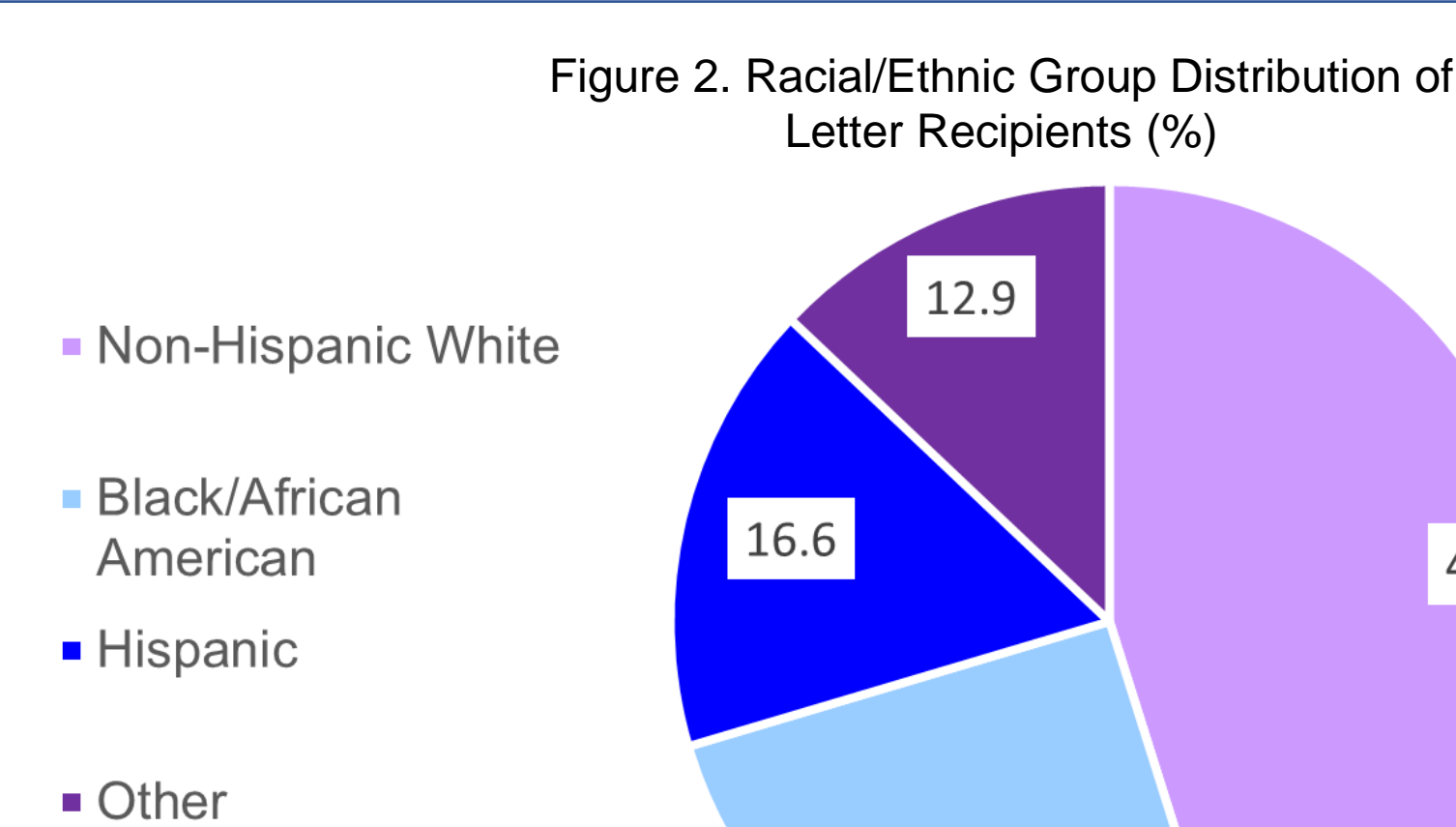


Figure 4. Overall Response Rate by Racial/Ethnic Group

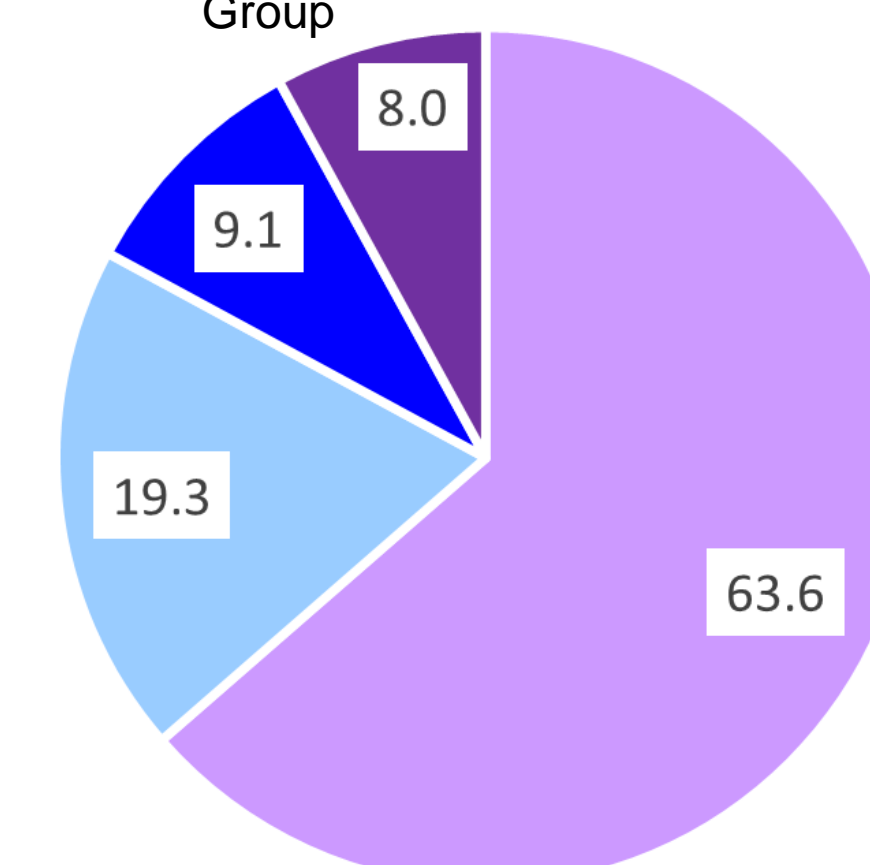


Table 1. Predictors of Response Rate (lowest response category underlined).

Variable	OR (95% CI)	p
Age (years)	1.01 (1.00, 1.02)	.040
Sex (0=male, 1=female)	1.49 (1.33, 1.68)	<.001
Race/Ethnic Group (White=Reference)		
--Black/AA	0.52 (0.45, 0.61)	<.001
--Hispanic	0.40 (0.33, 0.49)	<.001
--Other	0.48 (0.39, 0.59)	<.001
Neighborhood (Med Center=Reference)		
--Fort Bend	0.61 (0.51, 0.72)	<.001
--NW Houston	0.51 (0.43, 0.60)	<.001
--Pearland	0.68 (0.55, 0.85)	<.001
--Pasadena	0.60 (0.49, 0.72)	<.001

Conclusions

- Using an ethnically and racially diverse sampling frame, mailed invitations to participate in an AD prevention trial can yield a diverse patient population
- Oversampling of some groups to achieve desired recruitment targets can compensate for variations in response rate.
- Culturally and linguistically tailored materials may increase yields
- The significant role other demographic variables in response rate variability indicates the complexity of factors other than race/ethnicity that underlie recruitment yields in a specific clinical trial context
- Limitations: Some potentially relevant variables, such as household income and education, were not available for the analysis. Covid-19 surges throughout the recruitment period may have contributed to the response variability. Recruitment is 75% complete; final results may vary slightly.

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