

## FEATURED ARTICLE

# Screening and enrollment of underrepresented ethnocultural and educational populations in the Alzheimer's Disease Neuroimaging Initiative (ADNI)

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the Alzheimer's Disease Neuroimaging Initiative\*

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## Abstract

**Introduction:** An analysis of the ethnocultural and socioeconomic composition of Alzheimer's Disease Neuroimaging Initiative (ADNI) participants is needed to assess the generalizability of ADNI data to diverse populations.

**Methods:** ADNI data collected between October 2004 and November 2020 were used to determine ethnocultural and educational composition of the sample and differences in the following metrics: screening, screen fails, enrollment, biomarkers.

**Results:** Of 3739 screened individuals, 11% identified as being from ethnoculturally underrepresented populations (e.g., Black, Latinx) and 16% had <12 years of education. Of 2286 enrolled participants, 11% identified as ethnoculturally underrepresented individuals and 15% had <12 years of education. This participation is considerably lower than US Census data for adults 60+ (ethnoculturally underrepresented populations: 25%; <12 years of education: 4%). Individuals with <12 years of education failed screening at a higher rate.

**Discussion:** Our findings suggest that ADNI results may not be entirely generalizable to ethnoculturally diverse and low education populations.

## KEYWORDS

Alzheimer's disease, Alzheimer's Disease Neuroimaging Initiative, biomarkers, diversity, educational attainment, enrollment, ethnicity, race, screening

## 1 | BACKGROUND

Alzheimer's disease (AD) is a large and growing public health threat that is amplified in underrepresented populations (URPs) (ethnocultural [e.g., Black, Latinx, Asian Americans] and socioeconomically disadvantaged populations), which are disproportionately affected by AD. For URPs, AD disparities exist in prevalence, incidence, clinical dementia features, postdiagnosis survival, neuropathological features, and biological and medical risk factors.<sup>1,2</sup> For instance, there is greater AD prevalence and incidences in Black and Latinx populations.<sup>3-6</sup> However, AD risk *differs* across Latinx subpopulations.<sup>7-9</sup> All Asian American subpopulations have been found to have lower dementia incidences compared to non-Latinx Whites.<sup>10</sup> Lower education has been shown to be associated with a greater risk of dementia<sup>11</sup> and neighborhood deprivation has been associated with worse cognitive function in older adults<sup>12</sup> and accelerated neurodegeneration and cognitive decline in cognitively unimpaired middle- to older-aged adults.<sup>13</sup> The cause of these AD disparities is likely multifactorial and not well understood. It is believed that differences in environmental/contextual influences, and social, psychological, behavioral, genetic, and health factors contribute to disparities.<sup>1,14,15</sup>

However, our understanding of the cause of disparities is hindered by the widespread failure to successfully recruit and retain large study cohorts of URPs.<sup>16-19</sup> There is emerging evidence that URP status is associated with lower research interest and participation in in-clinic observational studies. Regarding ethnocultural differences in AD research interest and participation (enrollment, study task completion, biomarker collection, retention), Black individuals are less likely to participate in a hypothetical preclinical AD trial<sup>20</sup> and consent to brain donation.<sup>21</sup> Regarding research participation, the results of in-clinic studies suggest higher retention rates in non-Latinx Whites compared to other ethnocultural groups in Alzheimer's Disease Research Centers (ADRCs)<sup>22</sup> and other AD studies.<sup>23</sup> Compared to non-Latinx White participants, participants from ethnocultural URPs are less likely to have genetic samples available,<sup>24</sup> have lower ratio of completed brain donations to number of patients enrolled,<sup>25</sup> and are less likely to agree to lumbar puncture.<sup>26,27</sup> In an online AD-related registry, lower study withdrawal rates, higher completion and retention rates, and more enrollment in referral studies was found among participants identifying as non-Latinx White and of higher educational attainment.<sup>28</sup> A recent analysis of data from ADRCs also found higher educational attainment was associated with higher retention.<sup>22</sup> Participation of more URPs in AD research is crucial for producing more generalizable research findings, elucidating AD health disparities, and developing effective therapeutics for diverse populations.

The Alzheimer's Disease Neuroimaging Initiative (ADNI) is an ongoing, longitudinal, multicenter observational study with the overall goal of developing and validating clinical, imaging, genetic, and biochemical biomarkers for the use in AD clinical trials. Since inception in 2004, ADNI has generated >3600 publications. An analysis of the URP composition of ADNI participants, and the relationship between URP status and screening and enrollment is important to assess the generalizability of ADNI data to diverse populations, and to inform future efforts to increase diversity. One of ADNI's goals is to validate biomarkers,

### RESEARCH IN CONTEXT

1. **Systematic review:** The authors reviewed the literature using electronic data bases (e.g., PubMed) and search engines (Google Scholar). Previous publications have demonstrated that underrepresented ethnocultural populations (e.g., Latinx, Black, Asian) are under-enrolled in most Alzheimer' disease (AD) studies and that there are relationships between ethnocultural identity and screening, enrollment, and biomarkers. So far, few publications have addressed this issue in the Alzheimer's Disease Neuroimaging Initiative (ADNI) and focused on educational attainment.
2. **Interpretation:** ADNI reflects the on-going challenges with recruiting and enrolling underrepresented populations into most AD clinical research, especially multisite observational studies and clinical trials. Our findings highlight the need for ADNI to increase enrollment of underrepresented ethnocultural and educational populations to increase the generalizability of ADNI data to diverse populations
3. **Future directions:** In response, an ADNI Diversity Taskforce was recently established to evaluate the current efforts and facilitate improved recruitment approaches to make the current and future ADNI phases more ethnoculturally and socioeconomically representative.

such as amyloid, for clinical trials. It is therefore important to investigate biomarker distribution among ethnocultural groups in ADNI as differential distribution of biomarker positive individuals across ethnocultural groups could impact such biomarker validation studies. Therefore, the overall goal of this work was to describe screening and enrollment of ADNI participants between 2005 and 2020 and biomarkers, with a specific focus on ethnocultural and educational URP groups to assess the generalizability of ADNI data to diverse populations. The first aim was to describe the sociodemographic characteristics of everyone screened and enrolled in ADNI and compare the sociodemographic characteristics of screened and enrolled ADNI participants to the US Census. We tested the hypothesis that screen fail rates are higher in ethnocultural and educational URPs. The second aim was to describe and compare participant characteristics (including demographics and amyloid positivity) at the time of enrollment by ethnocultural and educational attainment groups.

## 2 | METHODS

### 2.1 | Sample

ADNI is an ongoing, longitudinal, multicenter study whose overall aim is to develop and validate clinical, imaging, genetic, and biochemical

biomarkers for use in AD clinical trials. Participants aged between 55 and 90 are recruited at >50 sites in the United States and Canada and undergo a series of initial and longitudinal assessments, including a clinical evaluation, neuropsychological tests, genetic testing, lumbar puncture, and magnetic resonance imaging and positron emission tomography (PET) scans. Participants are classified as cognitively unimpaired (CU) or as having mild cognitive impairment (MCI) or dementia due to AD. Some ADNI phases added subjective cognitive decline (SCD) as an additional baseline diagnostic group, and stratified MCI into early and late MCI. So far, there have been four phases of the ADNI study (1, GO, 2, and 3) and to the extent possible, participants were carried forward (also referred to as rolled over) from previous phases for continued monitoring, while new participants were added with each phase. This study focused on ADNI data across the four phases available by December 1, 2020 and included all unique individuals ever screened (N = 3739) and enrolled (N = 2286).

## 2.2 | Screening metrics

The following characteristics (age, sex at birth, ethnocultural identity, education), diagnostic groups (CU, MCI, AD), and ADNI cohort (1, GO, 2, 3) were collected during screening and were retrieved for this study. Participants were categorized as having failed or passed screening requirements. SCD were included in the CU diagnostic group. Early and late MCI were included in the MCI group.

## 2.3 | Enrollment metrics

Characteristics of all ever-enrolled participants were summarized, including ADNI phase at baseline, sociodemographic information (age, sex at birth, education in years, educational attainment groups, ethnocultural group), diagnosis group, family history of AD/dementia, biomarker data (apolipoprotein E  $\epsilon$ 4 carrier status, amyloid status). Age is presented as a continuous variable and the sex at birth variable differentiates between male and female. Education attainment was included as a proxy for socioeconomic status and is presented as continuous in years, as well as a two-level categorical variable ( $\leq 12$  years, >12 years of education), and the ethnocultural group variable included Latinx, non-Latinx Black, non-Latinx Asian, and non-Latinx White. Among participants with amyloid PET or cerebrospinal fluid, amyloid positive status required any one of: Pittsburgh compound B standardized uptake value ratio (SUVR) > 1.43 at any visit (only applies to ADNI-1), Flortbetapir SUVR > 1.11 at baseline, Flortbetaben SUVR > 1.08 at baseline, or Roche CSF A $\beta$  < 900 pg/ml at baseline; else participants were identified as amyloid negative. Diagnosis group included CU, MCI, and AD.

## 2.4 | US Census

The US Census data from the 2019 American Community Survey was used to determine nationally representative percentage estimates for the US population 60 years or older.<sup>29</sup>

## 2.5 | Statistical analysis

Summary characteristics of all ADNI participants who were ever screened, failed screening, and passed screening were tabulated (including frequencies, percentages for categorical variables and mean, standard deviation [SD] for continuous data). We assigned participants into five mutually exclusive ethnocultural groups: Hispanic/Latino (Latinx), not Hispanic/Latino Black or African American (non-Latinx Black), not Hispanic/Latino Asian (Non-Latinx Asian), not Hispanic/Latino Caucasian/White (non-Latinx White), and not Hispanic/Latino other racial group (Other). The "Other" group included participants who self-reported as American Indian, Alaska Native, Native Hawaiian/Pacific Islander, indicated more than one race, or refused to answer, each of which represented a relatively small sample size. We determined whether screened participants screen failed at equal rates between ethnocultural and education attainment groups using Pearson Chi-square test for categorical variables, Wilcoxon test for continuous variables among education attainment groups, and the Kruskal-Wallis test among ethnocultural groups. We also tested for the interaction of education and ethnicity on screening status (failed vs. passed) with logistic regression. Additionally, confidence intervals around the proportion of each ethnocultural group were used to compare the ADNI population to the US Census 60+ population by ethnoracial group. If appropriate, pairwise comparisons within groups were performed to determine whether there were any significant differences among ethnocultural groups. Odds ratios (ORs), 95% confidence intervals (CIs), and *P*-values were reported. All analyses were performed in R (version 4.0.4).<sup>30</sup> Due to the exploratory nature of this analysis, no adjustments were made for multiple comparisons and results are reported using point estimates, 95% CI, and unadjusted *P*-values.

## 3 | RESULTS

### 3.1 | Screening

Since the start of ADNI a total of 3739 individuals have been screened. Characteristics by screening status (failed vs. passed) are compared in Table 1. Of all screened individuals, the average age was 72.6 years (SD = 8.0), 1902 (52%) were male, 146 (4%) were Latinx, 67 (2%) non-Latinx Asian, 196 (5%) non-Latinx Black, 3170 (87%) non-Latinx White, the average years of education was 15.9 (SD = 2.8), 580 (16%) had  $\leq 12$  years of education, and most had MCI (1852; 51%); 1378 (37%) failed screening. Compared to the US Census 2019 American Community Survey for adults 60+ (Table 2), ADNI underrepresents Latinx ( $\Delta 5.2\%$ ), non-Latinx Black ( $\Delta = 4\%$ ), non-Latinx Asian ( $\Delta = 2.7\%$ ), and adults with education  $\leq 12$  years ( $\Delta = 27.7\%$ ). There were significant differences in age in years ( $P < .001$ ), years of education ( $P = .016$ ), educational attainment group ( $P = .006$ ), diagnosis group ( $P < .001$ ), and original ADNI cohort ( $P < .001$ ) between individuals who failed compared to those who did not fail. Individuals who failed screening were younger (71.65 [9.0] compared to 73.13 [7.4]) and had less education (15.75 [3.0] compared to 16.04 [2.75]) compared to those who did not

**TABLE 1** Participant characteristics of everyone screened

	Total screened (N = 3739) n (%)	Failed screening (N = 1378) n (%)	Passed screening (N = 2361) n (%)	P
Age in years <sup>a</sup>	72.6 (8.0)	71.7 (9.0)	73.1 (7.4)	<0.001 <sup>c</sup>
Sex at birth				0.122 <sup>d</sup>
Female	1756 (48%)	645 (50%)	1111 (47%)	
Male	1902 (52%)	652 (50%)	1250 (53%)	
Ethnocultural group <sup>b</sup>				0.756 <sup>d</sup>
Latinx	146 (4%)	49 (4%)	97 (4%)	
Non-Latinx Asian	67 (2%)	20 (2%)	47 (2%)	
Non-Latinx Black	196 (5%)	72 (6%)	124 (5%)	
Non-Latinx White	3170 (87%)	1113 (87%)	2057 (87%)	
Other	62 (2%)	26 (2%)	36 (2%)	
Education (years) <sup>a</sup>	15.9 (2.8)	15.7 (3.0)	16.0 (2.7)	0.016 <sup>c</sup>
Educational attainment group				0.006 <sup>d</sup>
≤12	580 (16%)	233 (18%)	347 (15%)	
>2	3064 (84%)	1050 (82%)	2014 (85%)	
Diagnosis group				<0.001 <sup>d</sup>
CU	1852 (51%)	752 (60%)	1100 (47%)	
MCI	1171 (32%)	319 (25%)	852 (36%)	
AD	592 (16%)	184 (15%)	408 (17%)	
Original ADNI cohort				<0.001 <sup>d</sup>
ADNI-1	1274 (34%)	452 (33%)	822 (35%)	
ADNI-GO	377 (10%)	234 (17%)	143 (6%)	
ADNI-2	1232 (33%)	409 (30%)	823 (35%)	
ADNI-3	856 (23%)	283 (21%)	573 (24%)	

<sup>a</sup>Mean (standard deviation) for continuous variables. N is the number of non-missing values.

<sup>b</sup>P-values are derived from tests excluding the Others' ethnocultural level.

<sup>c</sup>Wilcoxon test.

<sup>d</sup>Pearson test.

Abbreviations: AD, Alzheimer's disease; ADNI, Alzheimer's Disease Neuroimaging Initiative; CU, cognitively unimpaired; MCI, mild cognitive impairment.

**TABLE 2** ADNI enrolled participants compared to the US Census 2019 American Community Survey

	US Census	ADNI screened N = 3739	ADNI enrolled N = 2286
Ethnocultural group			
Latinx	9.2%	146 (3%–5%)	88 (3%–5%)
Asian	4.7%	67 (1%–2%)	46 (1%–3%)
Black	10.0%	196 (5%–6%)	114 (4%–6%)
White	74.6%	3170 (84%–86%)	2003 (86%–89%)
Other	4.1%	62 (1%–2%)	35 (1%–2%)
Educational attainment group			
≤12	43.7%	580 (14%–17%)	339 (13%–16%)
>12	56.3%	3064 (81%–83%)	1947 (84%–87%)

Note: For ADNI screened and enrolled, the number per group and 95% confidence interval for proportion are shown.

Abbreviation: ADNI, Alzheimer's Disease Neuroimaging Initiative.

fail screening. There was no significant difference in screen fail rate between non-URP and URP participants ( $P = 0.92$ ,  $CI = -0.05, 0.04$ ). We found no significant effect of the interaction between education and ethnicity on screening status ( $OR = 0.61$ ,  $CI = 0.27, 1.39$ ). Individuals with education  $\leq 12$  years failed screening at a significantly higher rate (0.4) compared to individuals with an education  $> 12$  years (0.34) ( $P = 0.01$ ,  $CI = 0.01, 0.10$ ).

## 3.2 | Enrollment

### 3.2.1 | Enrolled sample characteristics

Of all enrolled participants ( $N = 2286$ ), the mean age was 73.2 years, 1214 (53%) were male, 1947 (85%) had  $> 12$  years of education, 88 (4%) were Latinx, 46 (2%) were non-Latinx Asian, 114 (5%) were non-Latinx Black, and 2003 (88%) were non-Latinx White (and 35 Others). Compared to the US Census 2019 American Community Survey for adults 60+ (Table 2), ADNI enrollment underrepresents Latinx ( $\Delta = 5.1\%$ ), non-Latinx Black ( $\Delta = 4.7\%$ ), non-Latinx Asian ( $\Delta = 2.6\%$ ), and adults with education  $\leq 12$  years ( $\Delta = 28.7\%$ ). Sociodemographic, diagnostic, and biomarker characteristics are shown by ethnocultural groups (Table 3) and by educational attainment groups (Table 4). There were significant differences between ethnocultural groups in age in years, sex at birth, education attainment group, education in years, diagnosis group, and original ADNI protocol, as well as amyloid positivity status. There were also significant differences between educational attainment groups, age in years, sex at birth, diagnosis group, original ADNI cohort, and amyloid positivity status. We used multivariable regression analysis to test whether the statistically significant differences due to ethnocultural and education attainment groups on rates of amyloid positivity still existed after adjusting for age, sex, diagnosis group, and educational attainment or ethnocultural group, respectively (Table 5). Identifying as non-Latinx Asian was associated with having 64% reduced odds of being amyloid positive than non-Latinx White participants ( $P = 0.014$ ). Additionally, identifying as Latinx was associated with having 46% reduced odds of being amyloid positive than non-Latinx White participants ( $P = .031$ ). There were no statistically significant associations with educational attainment groups.

## 4 | DISCUSSION

The first main finding was that individuals identifying as ethnocultural and especially educational URPs are underrepresented among the screened and enrolled participants compared to the US Census. The second main finding was that lower education was associated with a higher screen fail rate. The third main finding was that after adjusting for age, sex at birth, education, and diagnosis, non-Latinx Asian and Latinx participants were less likely to be amyloid positive compared to non-Latinx White participants.

## 4.1 | Screening and enrollment of ethnocultural populations

Our first major finding was that only 11% of screened and enrolled participants identified as Latinx, non-Latinx Black, or non-Latinx-Asian. In contrast, the US Census reports 28% non-Whites aged 60+. This was expected, as despite strong efforts and initiatives and overall advancement in novel initiatives to improve outreach and recruitment of participant volunteers, ethnocultural URPs remain underrepresented in AD research.<sup>16-19,31</sup> Trial recruitment is often described as being one of the most prominent barriers to advancing our understanding of AD interventions<sup>18</sup> as it requires significant time, research and administrative personnel, and sufficient funds. Past studies show that recruitment of URPs is even more challenging due to population-specific barriers and facilitators of research participation. For example, common barriers include mistrust and fear (e.g., due to previous exploitation), stigma, racism, and competing demands and common facilitators include culturally tailored study designs, rapport, benefits to participation, altruism, education, and endorsement from the family regarding study participation.<sup>17,32</sup> To improve enrollment and retention of ethnocultural URPs, it is important to better understand and address these barriers and facilitators.

## 4.2 | Screening and enrollment by educational attainment

Only 16% of the screened and 15% of the enrolled participants indicated having  $\leq 12$  years of education, which substantially underrepresents this group of participants compared to adults aged 60+ from the 2019 US Census American Community Survey (44%).<sup>29</sup> Participants with lower education were even more underrepresented than ethnocultural URPs. As expected, ADNI participants from all ethnocultural populations were highly educated, ranging between 15.7 and 17.26 years of education, which is consistent with other AD-related cohorts.<sup>33</sup>

## 4.3 | Screen fails of ethnocultural populations

Contrary to hypothesis, our analyses did not show statistically significant differences in screen fail rates among ethnocultural URPs compared to non-Latinx White participants; however, these results will need to be interpreted with caution due to the small sample size. We expected that screen fails would be high among underrepresented ethnocultural groups due to higher incidence of medical comorbidities in URPs,<sup>34-37</sup> which are likely a byproduct of disparities in social determinants of health among URPs. Based on these findings, differences in screen fail rates and dropout do not appear to account for less ethnocultural diversity in ADNI. Potential explanations might be that ethnocultural URPs were not approached with the current recruitment strategies and/or that ethnocultural URPs were approached but did not advance past the prescreening process.

**TABLE 3** Participant characteristics at time of enrollment by ethnocultural groups

	Total N = 2286 n (%)	Latinx N = 88 n (%)	Non-Latinx Asian N = 46 n (%)	Non-Latinx Black N = 114 n (%)	Non-Latinx White N = 2003 n (%)	Others N = 35 n (%)	P
Age in years <sup>a</sup>	73.21 (7.22)	70.23 (7.51)	73.93 (8.06)	71.45 (7.37)	73.46 (7.13)	71.13 (7.40)	<0.001 <sup>b</sup>
Sex at birth							<0.001 <sup>c</sup>
Male	1214 (53%)	36 (41%)	24 (52%)	41 (36%)	1101 (55%)	12 (34%)	
Female	1072 (47%)	52 (59%)	22 (48%)	73 (64%)	902 (45%)	23 (66%)	
Education <sup>a</sup>	16.05 (2.76)	15.25 (3.25)	17.26 (2.14)	15.17 (2.94)	16.09 (2.72)	16.51 (2.80)	<0.001 <sup>b</sup>
Education attainment group							0.013 <sup>c</sup>
≤12 years	339 (15%)	17 (19%)	1 (2%)	24 (21%)	292 (15%)	5 (14%)	
>12 years	1947 (85%)	71 (81%)	45 (98%)	90 (79%)	1711 (85%)	30 (86%)	
Diagnosis group							0.033 <sup>c</sup>
Cognitively unimpaired	831 (36%)	35 (40%)	19 (41%)	58 (51%)	707 (35%)	12 (34%)	
Mild cognitive impairment	1056 (46%)	39 (44%)	17 (37%)	39 (34%)	944 (47%)	17 (49%)	
Alzheimer's disease	399 (17%)	14 (16%)	10 (22%)	17 (15%)	352 (18%)	6 (17%)	
Family history of AD/dementia							0.427 <sup>c</sup>
No	833 (41%)	27 (36%)	17 (42%)	44 (48%)	731 (41%)	14 (45%)	
Yes	1198 (59%)	49 (64%)	23 (57%)	48 (52%)	1061 (59%)	17 (55%)	
Original ADNI cohort							0.005 <sup>c</sup>
ADNI-1	819 (36%)	19 (22%)	14 (30%)	38 (33%)	740 (37%)	8 (23%)	
ADNI-GO	131 (6%)	8 (9%)	1 (2%)	4 (4%)	113 (6%)	5 (14%)	
ADNI-2	790 (35%)	31 (35%)	14 (30%)	34 (30%)	696 (35%)	15 (43%)	
ADNI-3	546 (24%)	30 (34%)	17 (37%)	38 (33%)	454 (23%)	7 (20%)	
Amyloid							0.002 <sup>c</sup>
Aβ+	372 (21%)	24 (34%)	12 (38%)	21 (25%)	312 (20%)	3 (11%)	
Aβ-	1425 (79%)	47 (66%)	20 (62%)	64 (75%)	1270 (80%)	24 (89%)	

Abbreviations: Aβ, amyloid beta; AD, Alzheimer's disease; ADNI, Alzheimer's Disease Neuroimaging Initiative.

<sup>a</sup>Mean (standard deviation) for continuous variables. N is the number of non-missing values. P-values are derived from tests excluding the Others' ethnocultural level.

<sup>b</sup>Tests used: Wilcoxon test.

<sup>c</sup>Pearson test.

#### 4.4 | Screen fails by educational attainment

As hypothesized, we found that individuals with education ≤12 years failed screening at a higher rate compared to individuals with education >12 years. These results are consistent with previous findings.<sup>36,38</sup> There is evidence that participants deemed as eligible in randomized clinical trials tend to be better educated, compared to ineligible participants.<sup>36</sup> One reason may be that individuals with lower educational attainment are less likely to be eligible due to the greater presence of health issues compared to more highly educated adults.<sup>38</sup> Individuals with lower education might have more comorbidities due to disparities in social determinants of health. The inclusion of individuals with lower education might be particularly important in AD prevention trials when considering the potential protective effect of education<sup>39</sup> on AD. These findings highlight the importance of targeted recruitment and engagement strategies for individuals from lower educational attainment backgrounds specifically.

Although this analysis focused on ethnocultural groups and education attainment, we interestingly also found that individuals who failed screening were younger and a higher proportion of individuals who screen failed were CU and screened in ADNI-GO compared to those who did not fail. This is likely because certain ADNI phases restricted eligibility to certain diagnostic groups. For example, ADNI-GO enrolled only individuals with early MCI. However, this is an interesting avenue for further investigation.

#### 4.5 | Amyloid status

We found that even after accounting for age, sex at birth, diagnosis, and education, there were associations between ethnocultural populations and amyloid status. Specifically, non-Latinx Asians and Latinx participants were less likely to be amyloid positive. These results must be interpreted with caution due the small and unrepresentative

**TABLE 4** Participant characteristics at time of enrollment by educational attainment

	Educational attainment ≤12 years N = 339 n (%)	Educational attainment >12 years N = 1947 n (%)	P
Age in years <sup>a</sup>	74.32 (7.08)	73.02 (7.22)	0.005 <sup>c</sup>
Sex at birth			0.001 <sup>d</sup>
Male	153 (45%)	1061 (54%)	
Female	186 (55%)	886 (46%)	
Ethnocultural group <sup>b</sup>			0.013 <sup>d</sup>
Latinx	17 (5%)	71 (4%)	
Non-Latinx Asian	1 (0%)	45 (2%)	
Non-Latinx Black	24 (7%)	90 (5%)	
Non-Latinx White	292 (86%)	1711 (88%)	
Others	5 (1%)	30 (2%)	
Diagnosis group			<0.001 <sup>d</sup>
Cognitively unimpaired	75 (22%)	756 (39%)	
Mild cognitive impairment	172 (51%)	884 (45%)	
Alzheimer's disease	92 (27%)	307 (16%)	
Family history of AD/dementia			<0.001 <sup>d</sup>
No	165 (53%)	668 (39%)	
Yes	145 (47%)	1053 (61%)	
Original cohort			<0.001 <sup>d</sup>
ADNI-1	162 (48%)	657 (34%)	
ADNI-GO	19 (6%)	112 (6%)	
ADNI-2	109 (32%)	681 (35%)	
ADNI-3	49 (14%)	497 (26%)	
Amyloid			0.009 <sup>d</sup>
Aβ+	204 (86%)	1221 (78%)	
Aβ-	34 (14%)	338 (22%)	

Abbreviations: Aβ, amyloid beta; AD, Alzheimer's disease; ADNI, Alzheimer's Disease Neuroimaging Initiative.

<sup>a</sup>Mean (standard deviation) for continuous variables. N is the number of non-missing values.

<sup>b</sup>P-values are derived from tests excluding the Others' ethnocultural level.

<sup>c</sup>Tests used: Wilcoxon test.

<sup>d</sup>Pearson test.

sample of ADNI. However, these results are consistent with previous research that found lower rates of amyloid positivity in aging minority cohorts (including Latinx and Asian participants).<sup>40</sup> However, these findings do not necessarily represent true shared biology or genetic make-up in this population. These findings stand in contrast to the overall increased risk of AD in the Latinx population<sup>3,5</sup> even though the risk differs across Latino ethnic groups.<sup>7–9</sup> Recent research found that Latinx individuals were more likely to have clinicopathologically defined cerebrovascular disease contributing to their dementia than non-Latinx White individuals,<sup>41</sup> which might be a potential explanation for lower rates of AD biomarkers despite an increased AD risk. The higher incidence of cerebrovascular disease among Latinx individuals might be due to social determinants of health that place them at greater risk for developing this pathology. This is a complex issue that needs to be explored further.

#### 4.6 | ADNI Diversity Taskforce

In response to the lack of diversity, an ADNI Diversity Taskforce was recently established to evaluate the current efforts and facilitate improved recruitment approaches to make the current and future ADNI phases more ethnoculturally representative. Some of the current accomplishments of the taskforce include:

- Establishment, funding, and support of 12 Diversity Recruitment Hubs for ADNI-3
- Changes to ADNI protocol to facilitate research participation (e.g., optional lumbar puncture and sharing of amyloid PET results)
- Hiring of an advertising agency that creates intensive, culturally tailored digital and print media marketing campaigns
- Development of a REDCap database to capture performance metrics of outreach efforts

**TABLE 5** Association between sociodemographic characteristics and amyloid positivity status

Predictor level	Amyloid positivity status (ref. level: negative)		
	Odds ratio	95% CI	P
Ethnocultural group (non-Latinx White)	1.000		
Latinx	0.544	[0.313,0.947]	0.031
Non-Latinx Asian	0.359	[0.159,0.812]	0.014
Non-Latinx Black	1.074	[0.627,1.839]	0.796
Age (years)	1.049	[1.030,1.068]	<0.001
Male	1.01	[0.786,1.298]	0.936
>12 years of education	0.787	[0.523,1.185]	0.252
Diagnosis group (dementia)	1.000		
Cognitively unimpaired	0.092	[0.052,0.163]	<0.001
Mild cognitive impairment	0.3	[0.169,0.535]	<0.001

Note: This section excludes the Others' ethnocultural groups due to low sample sizes in groups.

Abbreviation: CI, confidence interval.

#### 4.7 | Limitations

Because the sample sizes of underrepresented ethnocultural and educational attainment populations are small, interpretations of the findings should be made with caution. Further, due to small sample sizes in other ethnocultural populations (including multiple races, American Indian or Alaskan Native, and Native Hawaiian or Other Pacific Islander) we were not able to analyze these ethnocultural groups in detail. We were also not able to compare screen fail reasons due to small numbers of screen fails in underrepresented populations. A better understanding of how and which screen fail reasons affect the eligibility and inclusion of URPs is crucial to increase the external validity of future studies and ADNI. It would be important to closely monitor screen fail reasons in underrepresented populations in future ADNI phases. This analysis was limited to the data collected in the ADNI protocols. For example, ADNI does not delineate beyond the above listed ethnocultural population, which leads to the homogenization of otherwise heterogeneous populations, especially in the Asian and Latinx populations. A limitation of the ADNI recruitment and enrollment is that Spanish language testing over the entire study is only offered at a limited number of sites, and therefore is not truly representative of the US Census data. Further, the result for years of educational attainment variable must be considered with caution, as information about other aspects of education, for example, quality of education and adult literacy status, are missing. In addition, we were not able to investigate the influence of other sociocultural factors (e.g., immigration status, language, discrimination, location, income) on study screening and enrollment. The cognitive measure used as part of the classification of ADNI participants into diagnostic groups (CU, MCI, AD) did not include demographically adjusted norms that account for ethnocultural status

(e.g., the Logical Memory Test - Delayed Paragraph Recall Paragraph A used only education adjusted cut-offs). This is an important limitation of the current study and a high priority future direction for ADNI to use the best available tests and normative data to provide an evidence based, culturally responsive approach to the diagnostic classification of ethnoculturally diverse participants.<sup>42,43</sup> Future investigation will also look at participant drop-out within ADNI and between ADNI phases.

## 5 | CONCLUSION

In conclusion, this study shows that so far ADNI has mostly recruited and enrolled highly educated non-Latinx White older adults. This indicates that ADNI reflects the general recruitment and enrollment biases present in most AD clinical research and suggests that ADNI findings may not be entirely generalizable to diverse populations including those of ethnocultural diversity and of low education. This highlights the need for tailored enrollment and engagement strategies for URPs, which the newly established ADNI Diversity Taskforce aims to achieve.

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## CONFLICTS OF INTEREST

Dr. Ashford and Mr. Coker and declare no potential conflicts of interest. Dr. Raman has received grants from the National Institutes of Health, Alzheimer's Association, Eli Lilly, and Eisai. Dr. Raman serves as the Vice-Chair of the Alzheimer's Association San Diego/Imperial Chapter Board on a volunteer basis. Mr. Miller has received support from the National Institutes of Health and Eisai. These payments were made to his institution. Dr. Donohue declares that payments were made to his institution from all of the following grants: R01AG053798, U24AG057437, R01AG068324, R01AG061848, R01AG054029, R01AG063689, R01AG058468, U01AG057195, H8A-MC-LZAZ/ADC-040-A4 (ELI LILLY & CO.), R01AG047992, R61HD100973, U19AG024904. He has served on scientific advisory boards for Biogen, Eli Lilly, and Neurotrack; and has consulted for Roche. All payments were made to him. Dr. Donohue also received honorarium from University of Minnesota for a lecture. All travel to meetings was supported by NIH grants to his institution. He received payment from University of California San Diego for participating on a DSMB. His spouse is a full-time employee of Janssen. Dr. Okonkwo receives grant support from NIH for the present manuscript and attending meetings and/or travel. He is on the INS Board of Directors (Treasurer). M. Rivera Mindt declares all payments to institution: Ongoing Research NIH/NIGMS SC3GM141996 (PI: D. Byrd) Project Title: Health Disparities in Alzheimer's Disease: Intergenerational and Sociocultural Contributors to Dementia Literacy in Immigrant Latinx Families. This study will examine dementia literacy levels and the influence of generation status and sociocultural factors in Latinx immigrant family dyads. Role: Co-Investigator Total Award: \$346,500 NIH/NIA R13 AG071313-01 (MPIs: M. Rivera Mindt, R. Turner-II, M. Carrillo) 01/15/21 - 12/31/24



Project Title: Black Male Brain Reserve, Resilience & Alzheimer's Disease: Life Course Perspectives This three-year conference series will advance health disparities and cognitive aging research via focused and collaborative attention on increasing representation and engagement of Black males in ADRD research. Role: Co-Principal Investigator Total Award: ≈\$162,000 Genentech Health Equity Innovations 2020 Fund G-89294 01/01/21-12/31/24 (MPIs: M. Rivera Mindt, R. Nosheny & C. Hill) Project Title: Digital Engagement of Black/African American Older Adults in Alzheimer's Disease Clinical Research Using the Brain Health Registry The goal of this project is to improve participation of Black/African American older adults in Alzheimer's Disease research using novel, innovative community-engaged research techniques. Role: Co-Principal investigator Total Award: \$749,500 NIH/NIA R01AG065110 - 01A1 (PI: M. Rivera Mindt) 09/15/20-08/31/25 Project Title: Study of Aging Latinas/os for Understanding Dementia in HIV (S.A.L.U.D.) This is a longitudinal observational study of dementia rate and genetic, neuromedical, and sociocultural risk factors for dementia and changes in brain integrity in older HIV- & HIV+ Latinx adults. Role: Principal investigator Total Award: ≈\$3,329,120 NIH/NIA 5U19AG024904-14 (PI: M. Weiner) 07/15/20-07/30/22 Project Title: Alzheimer's Disease Neuroimaging Initiative (ADNI) The goal of ADNI is to discover, standardize, and validate biomarkers for AD treatment trials. Dr. Rivera Mindt will Co-Lead the ADNI Diversity Taskforce to advance diversity recruitment & related scientific goals. Role: Subcontract PI/Co-Investigator/Co-Lead of ADNI Diversity Task Force Total Award: \$96,040,840 Note. One of many ongoing ADNI grants NIH/NIA R01AG066471-01A1 (MPIs: A. Federman & J.P. Wisnivesky) 04/13/20-04/12/25 Project Title: Natural Language Processing and Automated Speech Recognition to Identify Older Adults with Cognitive Impairment (CI) This is a large (N = 1000) multi-site observational study of machine learning techniques to identify CI in a diverse sample of older adults. Total Award: \$4,278,550 Role: Co-Investigator Alzheimer's Association Research Grant AARGD-16-446038 07/01/17 - 06/30/20 (PI: Rivera Mindt; PI of subcontract to Mt. Sinai: J. Robinson-Papp) Project Title: Alzheimer's, Cerebrovascular, & Sociocultural Risk Factors for Dementia in HIV This cross-sectional study aims to understand the relative roles of HIV and aging in neurocognitive impairment of HIV+ Latinx older adults, including genetic, neuroimaging, laboratory, and neurocognitive evaluations. Role: Principal Investigator Total Award: \$165,000. Dr. Rivera Mindt declares to have been paid for the following: (1) Panel Moderator: Rivera Mindt, M., Hilsabeck, R. Marquine, M., and Trittschuh, E. (To be Presented 2021, June [delayed due to COVID-19 pandemic]). Hot Topics in Culture and Gender in Clinical Neuropsychology. Workshop to be presented at the American Academy of Clinical Neuropsychology annual meeting, Chicago, IL. (2) Invited Presentation: Savin, MJ & Rivera Mindt, M.G. (2021, May). Recommendations from the Rez: Guidelines and Future Directions for Neuropsychological Assessment among American Indian/Alaska Natives Adults. UCSD/San Diego VA Clinical Neuropsychology Seminar: Diversity Series in San Diego, CA. (3) Invited Presentation: Rivera Mindt, M. (2021, March). The Persistence of U.S. Brain Health Disparities: Moving Forward through Cultural

Neuropsychology. Harvard MGH Psychology Assessment Center Seminar; Boston, MA [virtual]; March 18, 2021. (4) Grand Rounds Presentation: Rivera Mindt, M. (2020, March [delayed due to COVID-19 pandemic]). Advancing Brain Health Equity in the 21st Century. University of Washington Department of Neurology Grand Rounds; Seattle, WA.; March 5th, 2020. (5) Keynote Presentation: Rivera Mindt, M. (2020, March). Improving Diagnostic Precision and Health Outcomes within the U.S. Latinx Population through Evidence-Based Neuropsychological Evaluation. Annual Conference of the Pacific Northwest Neuropsychological Society; Seattle, WA.; March 7th, 2020. (6) Invited Presentation: Rivera Mindt, M. (2020, January). The Vital Future of Clinical Psychology Through Diversity and Inclusion. Annual Conference of the Council of University Directors of Clinical Psychology; Austin, TX; January 18, 2020. (7) Invited Presentation: Rivera Mindt, M. (2019, October). Cultural Neuroscience in Society. National Academy of Sciences/Simons Foundation: The Science & Entertainment Exchange. Woodhull, MA. (8) Invited Presentation: Rivera Mindt, M. (2019, April). Cognitive Effects of Chronic Opioid Use, Treatment, and Implications for HIV & Health Disparities. Emory University HIV & Aging Conference. (9) Invited Presentation: Rivera Mindt, M. (2019, March). Brain & Cognitive Health in a Sociocultural Framework. Brown University Alpert Medical School, Department of Psychiatry and Human Behavior Grand Rounds. (10) Invited Presentation: Rivera Mindt, M. (2018, November). Neurocognitive diagnosis and care of older Latinx adults with neurocognitive impairment: A Culturally-tailored approach. Paper presentation at the Wisconsin Alzheimer's Institute/University of Wisconsin School of Medicine & Public Health 16th Annual Alzheimer's Disease Update Conference. (11) Invited Panelist: Rivera Mindt, M. (2018, Oct.). Developing multi-cultural competencies. Panel presentation at the 38th annual meeting of the National Academy of Neuropsychology, New Orleans, LA. (12) Invited Panelist: Rivera Mindt, M. (2018, Sept.). The Clinical Neuropsychologist: Increasing Diversity & Inclusion. Council of Science Editors, Technica Editorial Services Webinar. The Peer Review Ecosystem: Where Does Diversity & Inclusion Fit In? 2018 [accessed 2018 Oct 9]. <https://www.councilscienceeditors.org/resource-library/past-presentationswebinars/past-webinars/2018-webinar-3-the-peer-reviewer-ecosystem-where-does-diversity-inclusion-fit-in/>. (13) Invited Colloquium Presentation: Rivera Mindt, M. (2018, Sept.). Cultural neuropsychology: Implications for research and practice. Dept. of Psychology, Ohio University, Athens, OH. Support for attending meetings: NIH and Fordham University; paid to her if I needed to be reimbursed. Dr. Rivera Mindt has held the following roles: National/Regional Leadership 2021 - Present Advisory Board Member, ALL-FTD External Advisory Board 2021 - Present Advisory Board Member, Brown University Center for Alzheimer's Disease Research 2021 - Present Member, Centers for Disease Control and Prevention (CDC) BOLD Public Health Center of Excellence on Dementia Risk Reduction Expert Panel 2021 - Present Member, CDC/National Alzheimer's Project Act (NAPA) Physical Activity, Tobacco Use, and Alcohol Workgroup 2021 - Present Member, Einstein/Rockefeller/Hunter CFAR (ERC-CFAR) HIV and Mental Health Scientific Working Group 2020 - Present Board Member, Alzheimer's

Association NYC Chapter Board of Directors 2020 – Present Advisory Board Member, Society for Black Neuropsychology 2020 – Present Advisory Board Member, @SocialThatSupports (Chair: Dr. David Washington) 2019 Elections Committee, International Neuropsychological Society 2018 – Present Co-Founder & Co-Chair, Wisdom Workgroup for Indigenous Neuropsychology: A Global Strategy (Wisdom WINGS) 2018 – 2020 Continuing Education (CE) Program Committee, International Neuropsychological Society 2016 – 2020 President-Elect \* President \* Past-President (Elected Position), Hispanic Neuropsychological Society (HNS) Community 2020 – Present Board of Directors - Treasurer, Harlem Community & Academic Partnership 2019 – Present Older Adults Subcommittee Member, East Harlem Community Health Committee 2014 – 2019 Advisory Board Member, SMART University (NYC-based CBO for HIV+ women) 2013 – 2020 Board of Directors - Secretary, Harlem Community & Academic Partnership. Dr. Nosheny has received support from NIH (support to institution) for the present manuscript and grant from: NIH (grant to institution), California Department of Public Health (grant to institution), Genentech, Inc. (grant to institution), Alzheimer's Association (grant to institution). Dr. Nosheny received the following support for attending meetings: MCI 2020 symposium/Mt. Sinai: payment to her. Dr. Petersen reports support from Roche (consulting), Merck (consulting), Biogen (consulting), Eisai (consulting), Genentech (board member), DSMB, grants: U01 AG024904 U01 AG006786 P30 AG062677. He has received royalties/licenses from Oxford University Press UpToDate. Dr. Aisen reports research support through payments to his institution from Janssen, Lilly, Eisai, NIA, FNIH, Alzheimer's Association, and consulting fees from Biogen, Merck, Shionogi, Rainbow Medical, ImmunoBrain Checkpoint, Roche, Abbvie. Dr. Weiner is the Principal Investigator of NIH funded grants, which are administered through his institutions: UCSF and NCIRE. He received the following funding within the past 36 months, as Principal Investigator: NIH grant: 1RF1AG059009-01 administered through UCSF: \$6,240,949 total project – start date 9/1/2018 CA Dept. of Health grant: 19-10616 administered through UCSF: \$1,799,728 total project – start date 4/1/2020 NIH grant: 1R33AG062867-01A1 administered through UCSF: \$3,229,069 total project – start date 4/15/2020 NIH Subaward from Dr. Richard Gershon: 1U2CA060426-01 administered through NCIRE: \$65,036 annual directs only – start date 11/1/2018 NIH grant: 1R01AG058676-01A1 administered through NCIRE: \$3,646,420 total project – start date 9/30/2018. The following entities paid consulting fees to him directly, within the past 36 months: Baird Equity Capital, BioClinica, Cerecin, Inc., Cytox, Dolby Family Ventures, Duke University, FUJIFILM-Toyama Chemical (Japan), Garfield Weston, Genentech, Guidepoint Global, Indiana University, Japanese Organization for Medical Device Development, Inc. (JOMDD), Nestle/Nestec, NIH, Peerview Internal Medicine, Roche, T3D Therapeutics, University of Southern California (USC), and Vida Ventures. The following entity paid him for lecturing within the past 36 months: The Buck Institute for Research on Aging. The following entity paid for travel expenses for him to attend meetings within the past 36 months: University of Southern California (USC). He has served on Advisory Boards for: Acumen Pharmaceutical, ADNI, Brain Health Registry, Cerecin, Dolby

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