

Objective: Alzheimer's disease (AD) clinical trials lack diverse representation, limiting their generalizability. In addition, the clinical meaningfulness of observed changes during treatment may vary as a function of participant characteristics. Defining meaningful change in AD within diverse ethn racial groups is therefore greatly needed. Meaningful change in AD trials can be assessed by three different anchors: participants, informants, or clinicians. Previous research has suggested that estimations of the minimal clinically important difference (MCID) vary by disease severity, choice of anchor, and anchor agreement. These relationships have been studied primarily within non-Hispanic white (NHW) samples. This project evaluates anchor-based MCID within and across the three most prevalent ethn racial groups in the United States, non-Hispanic White (NHW), Hispanic/Latino (H/L), and Black/African-American (B/AA).

Participants and Methods: Data from the National Alzheimer's Coordinating Center Uniform Dataset (NACC UDS) were used to investigate MCID within older adults (ages 50+) diagnosed as cognitively normal or cognitively impaired due to suspected AD. Data were taken from all versions of the UDS and consisted of all available participants with two consecutive annual visits. The identified sample (N=22,043) is approximately 83.6% NHW, 4.7% H/L, and 11.7% B/AA. Participant, informant, and clinician anchor variables were utilized to compare proportions of anchor agreement within and across ethn racial groups. MCID on the Mini-Mental State Exam (MMSE) was estimated within each ethn racial group and compared across the independent variables of anchor agreement and disease severity (cognitively normal (CN), mild cognitive impairment (MCI), and dementia) in 2x3 ANOVAs.

Results: Participant age ($M = 71.56$, $SD = 9.03$) did not significantly differ across ethn racial groups; years of education significantly differed across groups, $p < .001$, with NHW ($M=15.83$, $SD=3.05$), H/L ($M=12.49$, $SD=5.01$), and B/AA ($M=14.42$, $SD=3.22$). Across all three anchors (participant, informant, clinician), unanimous agreement about the presence or absence of a decline in functioning was present in about 75.1% of the full sample. To further explore agreement differences across groups, anchor agreement was classified into a 3-level variable: 1) agreement that the participant remained stable over time, 2) agreement that the participant declined, and 3) disagreement. The

proportion of each level within each ethn racial group was significantly different, ($\chi^2(4, n = 22,043) = 179.16$, $p < .001$, $\phi = .09$, NHW (34.5% agreement-stable, 41.4% agreement-declined, 24.1% disagreement), H/L (30.5%, 42.6%, 26.9%, respectively), and B/AA (42.2%, 28.1%, 29.7%, respectively). MCID estimates on the MMSE followed similar trends within each ethn racial group. There was a significant main effect of disease severity, such that MCID estimates increased in magnitude with increasing disease severity. There were no significant main effects of anchor agreement for any ethn racial group. Within the NHW sample only, an interaction effect between diagnostic severity and anchor agreement was significant ($p = .007$).

Conclusions: Across ethn racial groups, MCID estimates on the MMSE are reliably influenced by the severity of disease. However, the benefit of anchor-based MCID estimates may vary by ethn racial group with respect to both anchor choice and use of anchor agreement. The origins of anchor disagreement and perceived stability in functioning warrant further exploration.

Categories: Dementia (Alzheimer's Disease)

Keyword 1: dementia - Alzheimer's disease

Keyword 2: cross-cultural issues

Keyword 3: psychometrics

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4 Advancing the science of recruitment and retention in ADRD clinical research among Hispanics/Latinos

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Objective: Inequity in Alzheimer's disease and related dementias (ADRD) clinical research is severely hindering our progress towards a cure for all, while inflating national costs. ADRD alone is currently costing United States 321 billion dollars in 2022, projected to increase to 1 trillion by 2050. Alzheimer's disease disproportionately impacts Black, Hispanic, Asian or Native Americans. Yet, ADRD clinical research to date

has not included equitable number of participants from communities of color to be representative of the U.S. population. Hispanic/Latinos currently represent 1% of ADRD clinical trials' samples despite representing 18% of the US population.

Participants and Methods: In our previous outreach and recruitment study with the Human Connectome Project – Aging, we attained a 11.35% recruitment success rate of Hispanics/Latinos living in Los Angeles County Districts. We implemented a comprehensive Spanish-English bilingual, multi-method, multi-setting community-academic engagement, outreach, and recruitment protocol with a focus on brain health literacy and ADRD biomarker research literacy.

Results: Whereas community educational engagement and outreach was the most efficient and highest interest turn-out recruitment strategy, 61% of engaged and interested Hispanic/Latinos (50 years old and older) were automatically excluded during the telephone screening due to English-language proficiency/fluency. Highest enrollment success rate was from UCLA mailing list, clinical registries, and referrals. Hispanics/Latinos successfully recruited were bilingual or multi-lingual, 83% identified white as their racial background, 85% attained higher education, and 70% resided in middle-to-high income levels areas.

Conclusions: Our results captured institutional barriers leading to a recruitment bias towards affluent Hispanics/Latinos with access to healthcare systems. Our applied science of recruitment and retention requires significant improvements in study design and methodology, tailored and targeted to communities' socio-ecological context. It also requires the extrapolation of generalizable theoretically informed mechanisms of successful engagement, recruitment, and retention strategies for replication and/or modification in other settings/locations, and countries.

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5 Cognitive, Emotional, and Functional Predictors of Clinical Trial Enrollment

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Objective: Objective: With participant recruitment being a top barrier to AD research progress, the rate of screen failure in Alzheimer's disease (AD) clinical trials is unsustainable. Although steps have been undertaken to consider solutions to the continued recruitment shortage, there is unfortunately minimal emphasis on reducing screen failure rates based on study inclusion criteria. Here we present information attempting to understand the cognitive, emotional, and functional features of individuals who failed screening measures for AD trials.

Participants and Methods: Method: The current study is a retrospective, cross-sectional analysis. Thirty-eight participants (aged 50-83) having (1) previously received a clinical diagnostic workup at a transdisciplinary cognitive specialty clinic and (2) previously screened for a specific industry-sponsored clinical trial of MCI/early AD (EMERGE) met inclusion criteria. Previously collected clinical data were analyzed to identify predictors of AD trial screen pass/fail status.

Results: Results: Of the 38 participants in the current study, 14 screen passed into this AD clinical trial, and 24 screen failed. Higher screen failure rates were significantly related to gender, with 83% of female participants screen failing this AD trial versus 45% of male participants. There was no difference in age or education between screen pass/fail groups, nor were differences present for performance on visual or verbal memory tasks, or the MOCA. Conversely, those participants screen failing this AD clinical