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## FROM THE ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE 2021

### ADDRESSING DIVERSITY IN ALZHEIMER'S CLINICAL TRIALS

*—NIA launches website for creating customizable recruiting materials  
for communities of color*

**DENVER, JULY 29, 2021** — A significant hurdle in developing therapeutics and care models for Alzheimer's disease that work for people of all ethnic and racial backgrounds is the recruitment and retention of traditionally underrepresented groups in clinical trials. At the [Alzheimer's Association International Conference® \(AAIC®\) 2021](#), in Denver and virtually, researchers shared new evidence-based insights into why people from communities of color do and do not choose to participate in clinical trials.

Also at AAIC 2021, the National Institute on Aging (NIA), part of the U.S. National Institutes of Health, launched a new online tool, Outreach Pro, to help researchers and clinicians increase awareness and participation in clinical trials on Alzheimer's disease and other dementias, especially among traditionally underrepresented communities.

“There is a well-recognized need for diversity in clinical trial populations to ensure diagnostics and treatments are safe and effective for everyone,” said Carl V. Hill, MPH, Ph.D., Alzheimer's Association chief diversity, equity and inclusion officer. “It's imperative that the Alzheimer's community is aware of the impact of historical racism, and also the current racial discrimination in health care that presents obstacles for inclusive participation in Alzheimer's trials. And, just as important, it is critical that we evaluate strategies that have been shown to be effective when recruiting historically underrepresented individuals and communities in these vital Alzheimer's research studies.”

Other key findings reported first at AAIC 2021 include:

- Individuals are most willing to volunteer for a clinical trial if they are invited to participate (85%), want to contribute to the goal of research (83%) or have a family member with the disease (74%).
- African American, Latino and American Indian respondents are significantly more likely to volunteer if asked by a person of the same race, and are more concerned than Whites about disruption of work and family responsibilities and availability of transportation and childcare.
- Commonly used Alzheimer's clinical trial exclusion criteria have the potential to disproportionately affect African Americans and Hispanics/Latinos, which may play a role in their reduced enrollment in research.

The Alzheimer's Association is leading two major clinical trials with a strong focus on diverse participation. The [New IDEAS study](#) is recruiting 2,000 Latinos and 2,000 African Americans to investigate the impact of a brain amyloid PET scan on clinical care outcomes, including diagnosis and treatment. The U.S. Study to Protect Brain Health Through Lifestyle Intervention to Reduce Risk ([U.S. POINTER](#)) study is a two-year clinical trial studying the effects of multi-component lifestyle interventions on risk of cognitive decline in a diverse population in the U.S.

### **NIA Launches Alzheimer's Research Recruiting Materials for Under-Represented Communities**

NIA has launched a new online tool to help increase awareness and participation in clinical trials on Alzheimer's disease and related dementias. Called Outreach Pro (V1.0), the tool allows researchers, clinicians, clinical trial administrators and staff to create and customize outreach materials such as websites, handouts, videos and social media posts with an emphasis on reaching traditionally underrepresented communities.

Using NIA's Outreach Pro, researchers and clinicians can make outreach materials from templates designed to:

1. Educate people about Alzheimer's and dementia.
2. Increase overall awareness of Alzheimer's clinical trials.
3. Provide information about a specific Alzheimer's or dementia clinical study open to recruitment.

Each template can then be tailored using a central library of messages, headlines, photos and text that have been extensively tested with individuals, including those representing diverse and underserved populations.

The development of Outreach Pro is an integral part of NIA's efforts to implement the [National Strategy for Recruitment and Participation in Alzheimer's and Related Dementias Clinical Research](#). Released in 2018, the national strategy was developed with facilitation by the Alzheimer's Association, with the goal of engaging broad segments of the public in Alzheimer's and dementia research, with a particular focus on underrepresented communities.

"It is critical that clinical trials have appropriate representation to ensure that we have a complete understanding of how well different therapies or approaches to dementia care work in different populations," said Holly Massett, Ph.D., Senior Advisor on Clinical Research Recruitment and Engagement at NIA, who oversees the implementation of the national strategy. "Outreach Pro was designed to provide well-tested and culturally appropriate outreach materials that resonate with diverse populations and encourage them to participate in clinical trials."

Outreach Pro's current library of content includes materials designed specifically for African American and Hispanic/Latino populations and is available in English and Spanish. Plans are underway to add materials developed for Asian Americans and Pacific Islanders in multiple languages by Fall 2021, and materials for American Indian and Alaska Native communities to be developed and added in 2022.

## **People More Likely to Participate Clinical Trials if Invited By Someone of the Same Race**

Dorothy Farrar Edwards, Ph.D., Faculty Director of the University of Wisconsin Collaborative Center for Health Equity and investigator and Outreach, Recruitment and Engagement Core Leader for the Wisconsin Alzheimer's Disease Research Center, and colleagues created the Voices Heard Survey to identify factors associated with willingness to participate in biomedical research. The survey was administered to a diverse sample of 406 Wisconsin residents, including White (n=100), African American (n=105), Latino (n=100) and American Indian (n=101) adults. The 96-item survey assessed trust in medical research and identified factors positively or negatively affecting willingness to participate in biomedical studies and clinical trials.

Factors most highly associated with willingness to volunteer for a study in the full group were (1) Invited to Participate (85%), (2) Research Goal (83%), and (3) Family Member with Disease (74%).

Significant differences were observed between the White and minority groups. Notably, African American, Latino and American Indian respondents are significantly more likely to volunteer for a research study if asked by a person of the same race, and they are more concerned than Whites about disruption of work and family responsibilities, availability of transportation, and childcare.

“We identified opportunities for tailored messaging designed to increase awareness of the value of Alzheimer's research participation,” Farrar Edwards said. “As we get better at recruiting diverse populations, it will increase the urgency to get the conduct of trials right.”

## **Are Common Exclusion Criteria in Alzheimer's Clinical Trials Keeping out Underrepresented Groups?**

In a first of its kind, systematic look at commonly used exclusion criteria in active NIA-funded Alzheimer's disease and related dementia clinical trials, NIA researchers suggest many criteria have the potential to inadvertently exclude African American and Hispanic/Latino participants. This new research reported at AAIC 2021 suggests a closer, collaborative look at the criteria may improve enrollment. Eligibility criteria are integral components of clinical trials, helping to ensure participant safety and reducing factors that may confound results.

Alexandra Mitchell, Clinical Research Coordinator at NIA, Holly Massett, Ph.D., NIA Senior Advisor on Clinical Research Recruitment and Engagement, and colleagues conducted a content analysis of 235 active NIA-funded Alzheimer's and dementia clinical trials to identify the most widely used criteria and their potential to disproportionately exclude African Americans and Hispanics/Latinos from the research. They identified 2,761 exclusion criteria and grouped them into 56 categories. On average, each trial had 11.75 exclusion criteria, with drug trials having the highest (18.14 per trial). Not surprisingly, “dementia/cognitive impairment” was the most common category (identified in 49% of trials). However, the next three most common categories included medical, neurological and psychiatric-related criteria that were classified as “broadly defined” such that they could introduce an unintentional level of subjectivity by investigators when determining participant eligibility. Additionally, the researchers found that 142 trials (60%) had at least one exclusion category that could disproportionately affect African American or Hispanic/Latino populations.

“This analysis is helping us ask an important question: Can we strengthen our criteria for clinical trials to maximize the number of eligible people from diverse and under-represented communities?” Mitchell said. “We hope the Alzheimer's community will take a closer look and can mimic the success in the oncology field where a concerted effort resulted in reworded, more equitable exclusion criteria.”

### **About the Alzheimer's Association International Conference (AAIC)**

The Alzheimer's Association International Conference (AAIC) is the world's largest gathering of researchers from around the world focused on Alzheimer's and other dementias. As a part of the Alzheimer's Association's research program, AAIC serves as a catalyst for generating new knowledge about dementia and fostering a vital, collegial research community.

AAIC 2021 home page: [www.alz.org/aaic/](http://www.alz.org/aaic/)

AAIC 2021 newsroom: [www.alz.org/aaic/pressroom.asp](http://www.alz.org/aaic/pressroom.asp)

AAIC 2021 hashtag: #AAIC21

### **About the Alzheimer's Association**

The Alzheimer's Association is a worldwide voluntary health organization dedicated to Alzheimer's care, support and research. Our mission is to lead the way to end Alzheimer's and all other dementia — by accelerating global research, driving risk reduction and early detection, and maximizing quality care and support. Our vision is a world without Alzheimer's and all other dementia®. Visit [alz.org](http://alz.org) or call 800.272.3900.

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- Holly A Massett, Ph.D., et al. Outreach Pro: The National Institute on Aging's (NIA) Online Tool for AD/ADRD Clinical Studies Recruitment and Engagement of Diverse and Underserved Populations. (Funder(s): National Institute on Aging, National Institutes of Health)
- Dorothy Farrar Edwards, Ph.D., et al. Tailoring Recruitment Message Content to Reach Diverse Communities for AD Research Participation. (Funder(s): National Institute on Minority Health and Health Disparities)
- Alexandra K. Mitchell, et al. Analysis of exclusion criteria in NIA-funded Alzheimer's Disease and Alzheimer's Disease-Related Dementias clinical trials. (Funder(s): National Institute on Aging, National Institutes of Health)