

Ensuring diverse participation in Alzheimer's clinical trial participants

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Enrolling representative populations in clinical trials for Alzheimer's disease is critical for finding treatments that will be safe and effective for all patients. African Americans and Latinos are disproportionately

affected by this disease yet are substantially underrepresented in trials of promising therapies. For example, an analysis of data from more than 100 clinical trials testing new treatments for Alzheimer's disease found that only 12% of participants were of any non-White race or Hispanic ethnicity.

That's unacceptable, say researchers from the Alzheimer's Clinical Trial Consortium (ACTC), an organization funded by the National Institute of Aging that provides infrastructure, resources and expertise for Alzheimer's [clinical trials](#) around the globe.

"The numbers of individuals living with Alzheimer's [disease](#) is increasing and this is a disease that disproportionately affects women and individuals belonging to racial and ethnic minority groups. But these groups and other underrepresented groups make up a small proportion of participants in trials," said Rema Raman, Ph.D., director of biostatistics and recruitment at the Alzheimer's Therapeutic Research Institute (ATRI) and co-lead of the recruitment unit for ACTC. "Better representation in clinical trials is critical in finding therapies that work for everyone."

The researchers identified obstacles to clinical trial participation and provided guidance on how to improve enrollment of underrepresented groups in a recent Viewpoint published in *JAMA Neurology*.

Address obstacles in eligibility

The authors' analysis of data on diversity in Alzheimer's disease clinical trials shed light on the fact that eligibility requirements for participation in Alzheimer's trials can disproportionately exclude people from certain groups. When enrolling patients in Alzheimer's disease research, potential participants are routinely given cognitive tests. Research showed that some ethnic and racial minorities were disproportionately

excluded more frequently in some trials because of the results of the cognitive tests, suggesting the need for tests that are culturally sensitive and unbiased.

"It is important to employ rigorous recruitment and retention science to identify the reasons individuals are being excluded from clinical trials and evaluate whether the selection criteria can be modified while still ensuring safety in the trial," said Raman, who is also a professor of neurology at the Keck School of Medicine of USC. "Evaluating the data to understand who is being included and excluded and the reasons why should be done repeatedly."

Accountability at the site

Most clinical trial sites are chosen based on several factors, but not necessarily including access to a diverse population. But even the sites in diverse areas typically fail to recruit diverse participants into clinical trials. One remedy suggested by the researchers is to work with sites to set specific goals to achieve in terms of diversity and give them the tools and resources to succeed.

"Across the board we are failing, even in places where we should be able to reach a more diverse group of participants," said Raman, noting that existing outreach efforts should be expanded upon with adequate resources for diverse recruitment.

The researchers also note that detailed diversity goals tailored to specific sites could increase site accountability. Especially in these NIH-funded networks, achieving goals could be key to continued membership.

New avenues for outreach

Ultimately, clinical trial sites, according to Raman, are going to need to build upon their existing outreach efforts with a focus on clinical trials participation.

Rather than trying to reach people only when they are in need of participants, the researchers suggested that trial sites should begin developing long-term partnerships in the community to aid with outreach when necessary.

"We are suggesting that sustained collaborations between clinical trials researchers conducting these trials and community-based researchers with established partnerships and trust in the community are needed," said Raman.

The researchers suggest that creating partnerships with key community organizations will improve trial participation through building trust and informing people in the community about the value of clinical trials. Such efforts, noted the researchers, will require substantial strategic planning and a commitment of resources.

"Alzheimer's disease is a huge financial and psychological drain on the individuals, their caregivers and society as a whole and these numbers are increasing," said Raman, adding that dementia cases in the U.S. are expected to double by 2050. "We need to find [sustainable solutions](#) and part of that must be improving the way we conduct inclusive clinical trials."

More information: Joshua D. Grill et al, What Should the Goals Be for Diverse Recruitment in Alzheimer Clinical Trials?, *JAMA Neurology* (2022). [DOI: 10.1001/jamaneurol.2022.2274](https://doi.org/10.1001/jamaneurol.2022.2274)

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