Effect of consenting clinician degree on screen fail rate in Alzheimer's Disease clinical trials

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Methodological Issue Being Addressed Can clinical research sites allow additional staff to go through the consenting process with participants in order to speed up recruitment of Alzheimer's Disease studies without negatively affecting screen fail rate?

Introduction Clinical trials on Alzheimer's Disease (AD) face exceptionally high screen failure rates, ranging from 88% in preclinical to 78% in prodromal AD clinical trials (Langbaum). These high screen fail rates can significantly impact trial timelines, costs, and ultimately slow the development of potential treatments for AD.

Irvine Clinical Research is a commercial site network in California that specializes in Alzheimer's Disease clinical trials. In order to accelerate the recruitment process, Irvine uses multiple clinicians of varying degrees of advanced education to consent and screen participants into trials.

It is possible that different consenting clinician degrees may lead to different screening outcomes due to differences in clinical interviewing expertise, familiarity with inclusion/exclusion criteria, communication style, or depth of relevant neuro-psychological training.

In this study, we examine the relationship between the type of degree of the consenting clinician (PhD, PsyD, or MD/PA) and subsequent screen failure rates.

Methods We examined screening data for all 272 participants who screened into one of two clinical trials on Alzheimer’s Disease conducted in 2023-2024. These two trials were separate but shared many similarities - both trials were testing the effectiveness of an anti-amyloid monoclonal antibody, recruited individuals who had mild cognitive impairment or mild AD, had similar exclusionary comorbidity criteria, and required similar scores on cognitive testing and positive amyloid PET. Additionally, recruitment for both studies was primarily through the same channel - online advertisements. Because the studies were looking for participants in the early stages of AD, there were very few candidates that had any prior experience with AD screening or clinical trials.

Of these 272 participants, 138 participants had consent obtained by a PsyD, 80 participants had consent obtained by a PhD in a relevant field, and the remaining 54 participants had consent obtained by an MD or PA.

Results A logistic regression analysis controlling for participant age, race, and trial was conducted on the collected data. Inclusion of the degree of the consenting clinician reduced the model deviance by X2 = 3.59 on two degrees of freedom, yielding a p-value of 0.166, which is not statistically significant.

When looking at the individual effects of the specific degrees from the regression analysis, none of the effects were significant. The largest effect was from participants who went through the consenting process with a PhD-level consenting clinician; these participants were very slightly more likely to screen fail (β = 0.759, z = 0.452, p=0.09).

Conclusion While there was no material difference in screen fail rate for consenting clinicians of different degrees, screen fail rate should not be the only consideration. For the purposes of collecting participant consent, the primary consideration should be proper and thorough understanding of the risks so that they can ethically consent. Beyond obtaining thorough consent, consent success rate - the percentage of eligible participants that a clinician is able to get into screening - should be considered and evaluated.

Study adherence / attrition rate or consent withdrawal rate could also be other measures to consider when delegating responsibilities at a research clinic.

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Keywords

Keywords
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