

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

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Background

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 the 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 distinct but had many similarities - they both tested an anti-amyloid monoclonal antibody treatment, they both recruited individuals who had mild cognitive impairment or mild AD, and both studies required certain scores on cognitive testing and positive amyloid PET.

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. Overall, 210 of the 272 participants did not randomize into the trial, giving a screen fail rate of 77.2% across both trials.

Consenter degree	Trial 1	Trial 2	Total
PsyD	27	111	138
PhD	29	51	80
MD or PA	10	44	54
Total	66	206	272

Consenting clinician degree for the different trials. A chi-square test for independence gives $p = 0.012$, so the trial is controlled for in the analyses.

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 $2 = 3.59$ on two degrees of freedom, yielding p -value of 0.166 which is not statistically significant.

When looking at the individual effects of the specific degrees, the largest effect size was from PhD-level consenting clinicians; participants who went through the consenting process with a PhD-level consenting clinician were very slightly more likely to screen fail ($\beta = 0.759$, $p = 0.09$).

Consenter degree	Randomized	Screen fail	Total
PsyD	34	104	138
PhD	13	67	80
MD or PA	15	39	54
Total	62	210	272

Screening outcomes for the participants based on the consenting clinician degree. $p = 0.226$ when testing for independence.

Model	Residual Deviance	Deg. Freedom
Demographics and trial only	276.35	265
Demographics, trial, consenter degree	272.76	263
Improvement	3.59	2

Deviance table comparing the consenter degree effect, $p = 0.166$

Conclusions

While there was no significant difference in screen fail rate for consenting clinicians of different degrees, screen fail rate should not be the only evaluation criteria when considering consenting clinicians. For the purposes of collecting participant consent, the primary consideration should be proper and thorough understanding of the risks so that the participant can ethically consent.

Beyond obtaining thorough consent, consent success rate - the percentage of potential participants that a clinician is able to get into screening - warrants consideration and evaluation. Other measures further along in the trial pipeline to consider when delegating responsibilities at a research clinic would be study adherence / attrition rate or consent withdrawal rate.

References

Langbaum JB, Zissimopoulos J, Au R, Bose N, Edgar CJ, Ehrenberg E, Fillit H, Hill CV, Hughes L, Irizarry M, Kremen S, Lakdawalla D, Lynn N, Malzbender K, Maruyama T, Massett HA, Patel D, Peneva D, Reiman EM, Romero K, Routledge C, Weiner MW, Weninger S, Aisen PS. Recommendations to address key recruitment challenges of Alzheimer's disease clinical trials. *Alzheimers Dement*. 2023 Feb;19(2):696-707. doi: 10.1002/alz.12737. Epub 2022 Aug 10. PMID: 35946590; PMCID: PMC9911558.

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