Recruitment of pre-dementia participants main enrollment barriers in a longitudinal amyloid-PET study

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Abstract:

Background: The mismatch between the limited availability versus the high demand of participants who are in the pre-dementia phase of Alzheimer's disease (AD) is a bottleneck for clinical studies in AD. Nevertheless, potential enrollment barriers in the pre-dementia population are relatively under-reported. In a large European longitudinal biomarker study (the AMYPAD-PNHS), we investigated main enrollment barriers in individuals with no or mild symptoms recruited from research and clinical parent cohorts (PCs) of ongoing observational studies.

Methods: Logistic regression was used to predict study refusal based on sex, age, education, global cognition (MMSE), family history of dementia, and number of prior study visits. Study refusal rates and categorized enrollment barriers were compared between PCs using chi-squared tests.

Results: 535/1856 (28.8%) of the participants recruited from ongoing studies declined participation in the AMYPAD-PNHS. Only for participants recruited from clinical PCs (n = 243), a higher MMSE-score (β = − 0.22, OR = 0.80, p < .05), more prior study visits (β = − 0.93, OR = 0.40, p < .001), and positive family history of dementia (β = 2.08, OR = 8.02, p < .01) resulted in lower odds on study refusal. General study burden was the main enrollment barrier (36.1%), followed by amyloid-PET related burden (PCresearch = 27.4%, PCclinical = 9.0%, X2 = 10.56, p = .001), and loss of research interest (PCclinical = 46.3%, PCresearch = 16.5%, X2 = 32.34, p < .001).

Conclusions: The enrollment rate for the AMYPAD-PNHS was relatively high, suggesting an advantage of recruitment via ongoing studies. In this observational cohort, study burden reduction and tailored strategies may potentially improve participant enrollment into trial readiness cohorts such as for phase-3 early anti-amyloid intervention trials.

Published online: 2 November 2023

Alz Res Therapy

https://doi.org/10.1186/s13195-023-01332-4