

Risk Evaluation and Education for Alzheimer's Disease – the Study of Communicating Amyloid Neuroimaging (REVEAL-SCAN)

NCT029599489

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Power Calculation:

Our objective was to achieve 80% power to detect a difference of moderate effect size (0.4-0.6 SD units) on the primary outcome of ADCS-PACC mean score between the A+D- and A+D+ groups at 6 months.

Assuming a PACC standard deviation of 2.2 (Donohue et al, JAMA Neurology, 2014. Doi: JAMA Neurol. 2014;71(8):961-970. doi:10.1001/jamaneurol.2014.803), 60 individuals per group would provide 80% power to detect a difference of 1.15 PACC units (0.57 SD units) between A+D- and A+D+ at 6 months.

Based on this calculation, we set an initial target to enroll n=60 in each of the 4 groups (A+D-, A+D+, A-D, A-D+). We anticipated a 50% rate of elevated amyloid and equal randomization between disclosed and non-disclosed arms, and a dropout rate of approximately 10%. Thus we planned to enroll 270 total participants and achieve 240 completed 6 month visits to reach our group enrollment targets of n=60.

Due to a much lower than anticipated rate of amyloid positivity, as well as limitations of time and resources, we reduced the enrollment target for each group to n=50. This sample size provides 80% power to detect a difference of 1.25 PACC units (0.52 SD units) between A+D- and A+D+ at 6 months, which is still within the moderate effect size range.