

# A randomized study of methods for returning APOE and pTau-217 results: eSMARTER design and recruitment

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## SUBMISSION DETAILS

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**Methodological Issue Being Addressed** Disclosing Alzheimer's disease (AD) genetic and biomarker information is increasingly common, particularly in clinical trials and observational research. As results become relevant for clinical care and more people must learn their results, scalable approaches to returning AD-related information are needed.

**Introduction** To date, current clinical trial practices for returning AD genetic and biomarker results focus on implications for trial eligibility, as opposed to risks for AD or treatment side effects. Existing guidance from observational studies returning AD-related, which provide more information about results than clinical trials, is often resource-intensive and requires a clinician to return results. Increasing ethical, practical, and social demands for returning AD-related information inspired the development of the Evaluation of Self-Mediated Alternatives for Risk Testing Education and Return of Results (eSMARTER) Study. eSMARTER is an ongoing randomized, fully decentralized, non-inferiority clinical trial that will evaluate scalable digital methods for self-mediated return of APOE and novel plasma pTau-217 results and characterize the individual impact (#NCT06459583).

**Methods** Participants complete all visits and assessments at-home. Study events include screening, APOE disclosure, and optional plasma pTau-217 disclosure, with additional timepoints for measurement collection. Participants aged 60-80 are randomized to receive their APOE and pTau-217 results via clinician-mediated telehealth videoconference (usual care) or self-mediated online platform. Our primary hypothesis is self-mediated APOE disclosure will result in non-inferior outcomes compared to clinician-mediated disclosure. The three primary outcomes are changes in anxiety, AD-related knowledge, and disease-specific distress. For the primary analyses, we will apply non-inferiority tests to examine if self-mediated disclosure provides equivalent or improved outcomes compared to usual care. Our secondary hypothesis is learning APOE and pTau-217 results will affect participants' mood, self-perception of disease risk, and quality of life. We hypothesize participants who learn results indicating more risk will report increased, but not clinically significant psychological distress and increased disease risk. We hypothesize there will not be changes in quality of life. We will examine change scores of the validated mood, self-perception of disease risk, and quality of life measures from pre- to post-disclosure.

**Results** Recruitment and enrollment were completed in February 2025. Data collection will conclude November 2025. 659 participants learned their APOE results (218 via clinician, 441 via digital platform). 505 participants learned their pTau-217 results (158 via clinician, 347 via digital

platform). Full results are forthcoming. In addition to results from the primary and secondary analyses, insights from conducting a national, decentralized, randomized trial will also be shared.

**Conclusion** The development and deployment of digital platforms to return AD-related risk information is a crucial step to meet expected demand and do so in a clinically translatable, responsible way. eSMARTER is an opportunity to understand the benefits and limitations of utilizing digital platforms to return APOE and pTau-217 results and characterize how people respond to and understand such information. The digital platforms developed for eSMARTER will be available to researchers and clinicians seeking to return AD-related results in research and clinic. All data and samples collected will be made available for public sharing.

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