



Ethical challenges in preclinical Alzheimer's disease observational studies and trials: Results of the Barcelona summit

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Alzheimer's disease (AD) is among the most significant health care burdens. Disappointing results from clinical trials in late-stage AD persons combined with hopeful results from trials in persons with early-stage suggest that research in the preclinical stage of AD is necessary to define an optimal therapeutic success window. We review the justification for conducting trials in the preclinical stage and highlight novel ethical challenges that arise and are related to determining appropriate risk-benefit ratios and disclosing individuals' biomarker status. We propose that to conduct clinical trials with these participants, we need to improve public understanding of AD using unified vocabulary, resolve the acceptable risk-benefit ratio in asymptomatic participants, and disclose or not biomarker status with attention to study type (observational studies vs clinical trials). Overcoming these challenges will justify clinical trials in preclinical AD at the societal level and aid to the development of societal and legal support for trial participants.

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