

The scientific and ethical challenges of precision medicine for the brain

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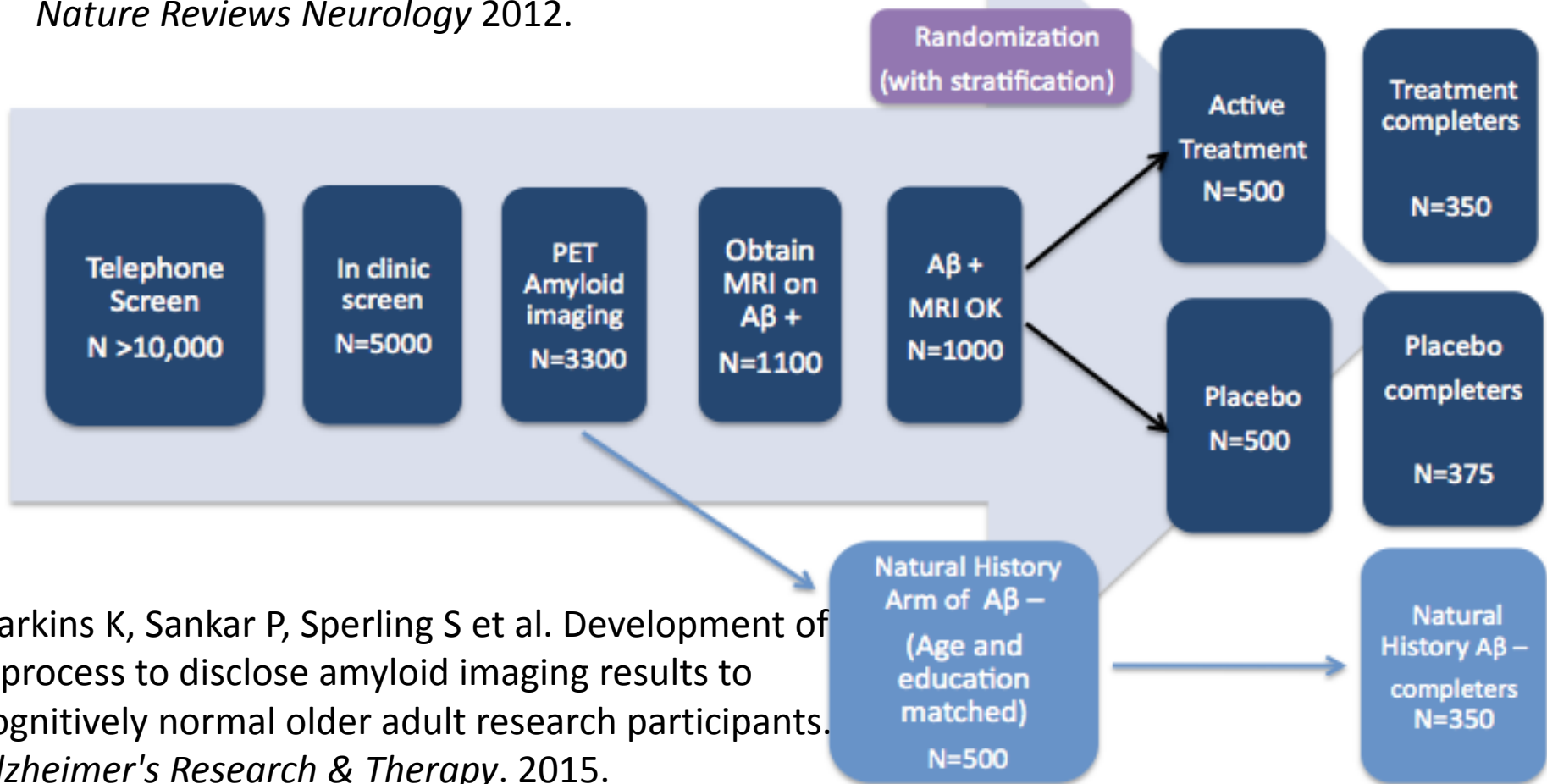
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The Anti-Amyloid in Asymptomatic Alzheimers Study

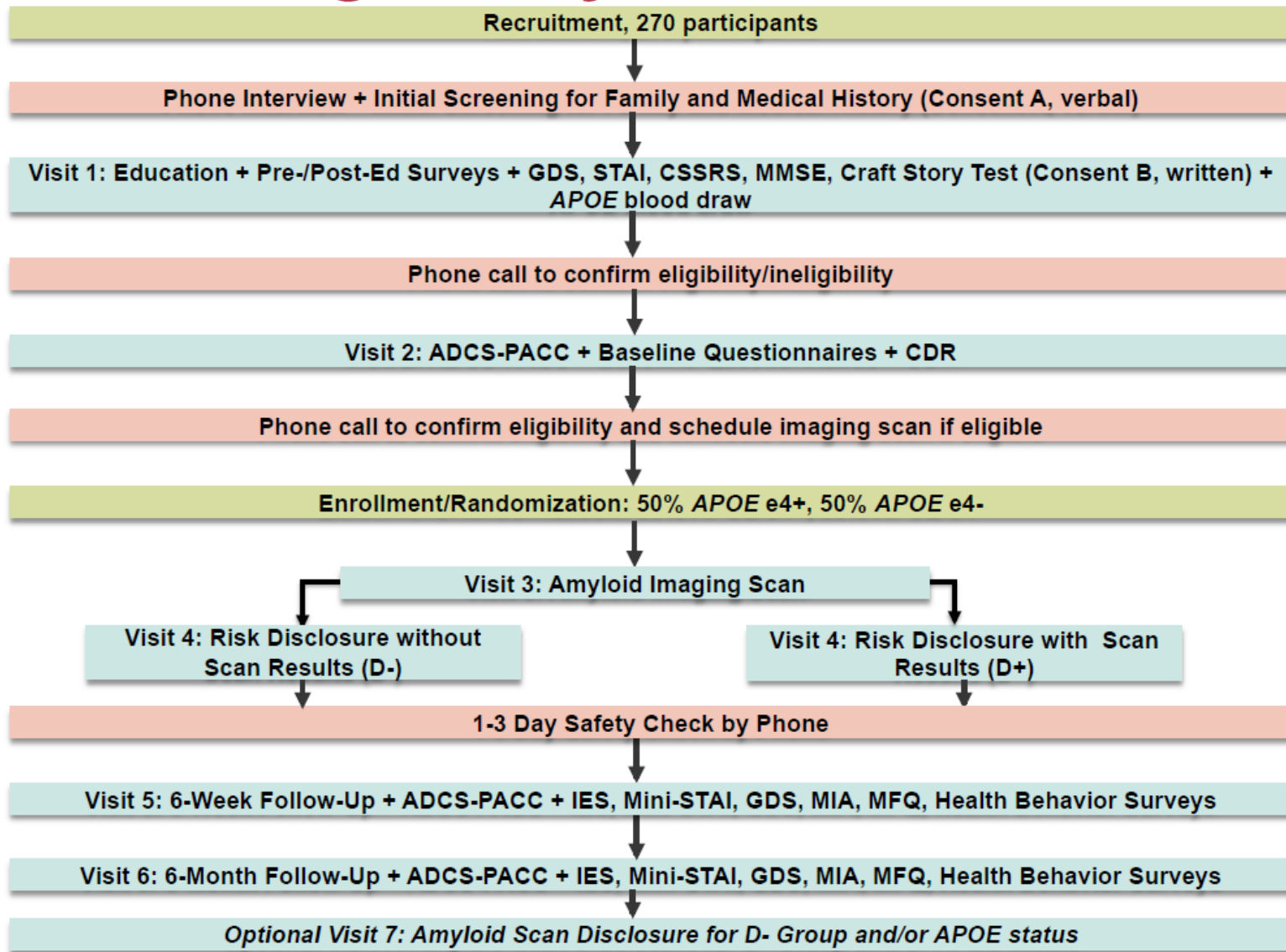
Sperling RA, Karlawish J, Johnson KA:
Preclinical Alzheimer disease-the challenges ahead.
Nature Reviews Neurology 2012.



Harkins K, Sankar P, Sperling S et al. Development of a process to disclose amyloid imaging results to cognitively normal older adult research participants. *Alzheimer's Research & Therapy*. 2015.

Study of Knowledge and Reactions to Amyloid Testing (SOKRATES).
IIRG, Alzheimer's Association.

Impact of disclosing amyloid imaging results to cognitively normal individuals



CONNECT 4 *APOE* Design

Generation Study potential participants selected to come to the site for *APOE* disclosure and screening



Anticipate 3000 US participants
Baseline assessment (T0): Primary outcomes = 1. Genetic knowledge, 2. disease-specific distress, 3. satisfaction with genetic services



RANDOMIZED

TELEPHONE DISCLOSURE
(at the study site)
Post disclosure assessments*

VIDEOCONFERENCE DISCLOSURE
(at the study site)
Post disclosure assessments*

Is videoconferencing superior to telephone for remote disclosure of *APOE4* genotype results?
Are there differences by test result or other patient factors?

* Post disclosure assessments per Generation Study at 2-7 days (T1), 1 month (T2), 6 (T3) and 12 (T4) months.

What else do we need to do?

- Develop best practices for disclosing to patients a gene/biomarker result: expertise, venue, and words
 - Who's an "Alzheimer's expert"
 - in person, telephone, video
 - Elevated/not elevated, positive/negative, AD, @riskforAD....
- Improve insurance, employment and privacy protections for persons who are gene or biomarker "positive"
 - Arias and Karlawish. Neurology. 2014

What else do we need to do?

- What risks are acceptable to receive a gene/biomarker result and take a drug?
 - biomedical harms: body & brain
 - social & psychological harms
- What is the value of an intervention that over ~24 to 36 months changes performance on a composite measure of cognition?