Human: Improving clinical trial methodology

T2 protect AD: Achieving a rapid recruitment timeline in a multi-site clinical trial for individuals with mild-to-moderate Alzheimer’s disease

Andrea Z. LaCroix1 | Aladdin H. Shadyab2 | Genevieve Matthews2 | Daniel Bennett2 | Alexandre Shadyab2 | Lia Donahue3 | Irfan Qureshi3 | Howard H. Feldman4

1 University of California, San Diego, La Jolla, CA, USA
2 University of California, San Diego, San Diego, CA, USA
3 Biohaven Pharmaceuticals Inc, New Haven, CT, USA
4 University of California, San Diego, CA, USA

Correspondence
Andrea Z. LaCroix, University of California, San Diego, La Jolla, CA, USA.
Email: alacroix@ucsd.edu

Abstract

Background: Preservation or improvement in cognition in Alzheimer’s disease (AD) is a public health priority. In 2018, there were 30 drugs in phase II and III AD trials1, increasing to 50 in 20192. However, AD trial recruitment is oft-cited as slowing down research advancements3,4. The T2 Protect AD Trial (T2), is a multi-site, randomized, placebo controlled, 52-week trial testing troriluzole, a glutamate modulator. T2 was designed as a proof of concept clinical trial with an estimated sample size of 336 participants.

Method: T2 is coordinated by the ADCS, and includes 44 US academic and private medical clinics specialized in AD research, treatment, and care. The trial (NCT03605667) includes participants with mild-to-moderate AD, 50-85 years old, stable on AD medication(s), with MMSE 14-24 and MRI findings consistent with AD. There are no AD biomarker inclusion criteria. The trial recruitment toolkit included flyers, brochures, press release, FAQ, infographics, video, and a website. The recruitment budget was divided between the central ADCS effort and individual sites. The ADCS effort included creative design services, social media outreach, telephone prescreening, development of news stories, and advertising placement.

Result: Sites screened 736 individuals, randomizing 350. Fourteen sites exceeded their enrollment goal of 10 participants and the top two sites randomized 25 and 20 participants. 98% of participants were randomized during an intensively supported 10-month rapid recruitment period, that was initiated when 21/44 sites were actively recruiting (Figure). The randomization rate, defined as the number randomized, divided by the number of active site recruitment months, ranged from 0 (1 site) to 4.0 per month, with an overall rate of 0.87 per month. Sites enrolled 75% of the cohort through their existing site recruitment infrastructure, including waiting lists and internal referrals. 25% came from news media reports, paid advertising, word-of-mouth, and outside physician/organizational referrals. Social media advertising was not a significant source of participants.
Conclusion: This trial in mild-to-moderate AD achieved among the highest site recruitment rates reported in ADCS investigational new drug trials in the last 20 years. Its success was primarily achieved through site network resources, however central recruiting efforts contributed significantly.