

Preliminary Results of a Digital Pilot to Improve AD Trial Retention by Managing Caregiver Stress

Introduction

Retention in Alzheimer's disease (AD) trials is challenging. In many trial dyads, study partners are also engaged as Family Caregivers (FCs) for the subject. This dynamic adds a unique set of responsibilities and stressors that increase the risk of trial withdrawal. The average retention rate for mild cognitive impairment (MCI) AD trials is 71.6%, **mild-to-moderate AD trials 77.7%**, and moderate-to-severe and severe AD trials 75.4%.

Navigating Aging Needs LLC (NAN) and ClinCloud Clinical Trials have partnered to pilot a virtual support service to improve AD trial retention by stabilizing or reducing the burden of FC stress. These are preliminary results from a sample of six participants over a six-month period.

Objectives

1. Increase the rate of study retention in AD clinical trials
2. Reduce early termination due to FC burden of stress, as measured by the Zarit Burden scale short form

Methods

- Family caregivers volunteering as study partners in phase 3 trials from two key sponsors were offered a 12-month subscription to the Navigating Aging Needs (NAN) Program.
- Sponsors funded subscription costs through invoiceable retention fees per each randomized subject. Subscriptions included weekly Zoom sessions with a personal NAN Navigator (licensed social worker).
- The initial meeting between each FC and social worker consisted of an assessment that included 80 questions on the AD patient's medical, emotional, social, and legal/financial well-being and the validated battery of 12 questions comprising the Zarit Burden scale short form.
- Following the initial meeting, the social worker provided the FC with a plan that identified areas of risk that "need attention" or "may need attention," along with resources to address identified needs.
- For the subsequent six months, the social worker met with the FC weekly to provide guidance on how to resolve areas identified as high-risk and discuss other relevant issues as they arose.
- At each session, FCs were queried about their current satisfaction with clinical trial participation. As needed the social worker engaged site personnel to mitigate areas identified as "stress of participation."
- The social worker reassessed the family caregiver's Zarit Burden Score twice, after three months and six months of guidance and support.
- FCs had access to round-the-clock availability of resources on the nanforcaregivers.com website.

Results

Preliminary Results

1. Clinical trial site + NAN = Increased trial retention:
Overall study retention is 83.3% (5/6)*
2. Reduced early termination due to the burden of FC stress:
Discontinuation due to caregiver burden of stress: 0

*One study termination was due to hospice placement.

All six family caregivers showed improved or stable Zarit Burden scale scores

Zarit Burden scale scores: baseline and 6 months

Caregiver Number	Baseline Zarit	6 Month Zarit	
5	18	12	IMPROVED
6	18	12	IMPROVED
3	29	4	IMPROVED
4	6	5	STABLE
1	7	7	STABLE
2	22	23	STABLE

Zarit Burden score short form is a validated self-reported caregiver survey that evaluates a caregiver's burden of stress. Scores below 10 show low burden, 10-20 show moderate burden and scores higher than 20 show high burden.

Data are available for the first six FCs to enter the pilot. (We continue to enroll additional family caregivers in this ongoing program.)

Additional results demonstrate three instances of reducing FC "stress of participation"

MRI scheduling for travel

- A caregiver told their NAN Navigator that they would have to leave the trial if the trial site could not accommodate their request to reschedule an upcoming MRI that interfered with a long-planned trip. The NAN Navigator helped by speaking with the clinical trial site team and the schedule was adjusted.

Medication storage difficulty

- A caregiver heading out on a trip was at risk of compromising the investigational product because they did not have a way to keep it at the required temperature. The NAN Navigator found a solution, cleared it with the clinical trials team, and the caregiver and subject enjoyed their road trip while staying on schedule for all trial activities.

Communication

- A caregiver reported feeling frustrated with some communication difficulties he noticed between the subject and the clinical trials team. The NAN Navigator provided recommendations to the clinical trials team to improve communication with the subject.

Conclusion

Preliminary results show that:

- Providing NAN support for FCs results in better-than-industry average study retention (83% vs. the industry average for mild-to-moderate AD trials of 77.7%).
- Monitoring the "stress of participation" and intervening as needed reduces early trial termination resulting from FC burden of stress.

Based on these early results, NAN and ClinCloud are working together to expand the number of FCs receiving virtual support services, to better understand the impact of this intervention.