Protocol Title: User-Led Meaningful Activity and Early-Stage Dementia

Document Title: Statistical Analysis Plan

NCT: NCT05159869

Document Date: 21AUG2025

Statistical Analysis Plan

The study followed a randomized, two-arm parallel design. Seventy (70) dyads comprising community-dwelling individuals with early-stage dementia and their primary caregivers were assigned to treatment or wait-list control. Treatment group participants received the co-designed meaningful activity intervention, and all dyads were reassessed at four months from baseline. After four months, wait-list control dyads received the same intervention and were retested four months later (i.e., eight months from baseline).

Analyses were based on the Intent-To-Treat (ITT) principle, including every patient who was randomized. All tests were performed at two-tailed significance $\alpha=0.05$. First, chi-squared and t-test tests were used to compare intervention and control dyads on baseline characteristics. The primary hypothesis held that a co-designed meaningful activity intervention would significantly decrease the frequency and intensity of neuropsychiatric symptoms (NPS) and slow cognitive decline across multiple domains (i.e., memory and learning, executive function, visuospatial abilities, attention, language, processing speed). The secondary hypothesis was that a co-designed meaningful activity intervention would significantly increase emotional well-being (e.g., reduce depression and anxiety) and strengthen self-identity. To test the hypotheses, main treatment effects at four months were examined using analysis of covariance (ANCOVA). Given prior research linking caregiver characteristics to ratings of neuropsychiatric and psychosocial outcomes, caregiver sex, race/ethnicity, education, and relationship to the person living with dementia (PLWD) were identified a priori as covariates. Standardized effect sizes (*d*) were calculated as the adjusted mean difference between groups divided by the square root of the model's mean square error (MSE).

To evaluate whether wait-list control participants derived benefits comparable to those of the meaningful activity group after receiving the intervention, change scores were examined from 4 months (T2) to 8 months (T3) in the wait-list control group and compared with change scores from baseline (T1) to 4 months (T2) in the meaningful activity intervention group. Analyses were conducted using the same ANCOVA framework applied in the primary analysis. It was hypothesized that the magnitude of treatment effects would be similar across groups, reflecting replication of benefit, and therefore the between-group difference in change would not be statistically significant.