

**Study Title:** A pilot cluster randomized controlled trial of a phone intervention supporting family caregivers of people living with dementia in Vietnam: Resources for Enhancing Alzheimer's Caregiver Health in Vietnam (REACH VN)

**NCT#:** NCT05481320

**Document Date:** October 17, 2022

**Document Type:** Statistical Analysis Plan

### *Statistical Analysis Plan*

RCT outcomes include caregiver burden (primary) and depressive/anxiety symptoms (secondary). Preliminary analyses will compare the two groups at baseline on participant characteristics and primary outcomes using t-tests or chi-squared tests as appropriate; non-parametric versions will be used if needed. For each outcome, the primary assessment of efficacy will be based on intent-to-treat analyses. Difference scores on the outcomes between the two assessments will be computed. Within-group change will be assessed with a paired t-test or the Wilcoxon signed rank test, as appropriate, while between-group differences in change will be assessed with a two-sample t-test or the Wilcoxon rank sum test. If groups differ at baseline, analysis of covariance will be used with the 3-month assessment as the outcome and the baseline assessment as a covariate; group will be the primary predictor of interest and any additional participant characteristics found to be different at baseline will also be considered as covariates. Transformations or generalized linear models for non-normal data will be considered if model assumptions are violated. The data were imported into the REDcap database and analyzed using SAS statistical software. A p-value less than 0.05 is considered statistically significant.

Power analysis: With 30 participants per group, we will have 80% power to detect a difference as small as 0.64 standard deviations between the groups, assuming a one-sided test (as this is a pilot study) and alpha=0.05. If alpha is reduced to 0.025 to account for the two outcomes, the minimum detectable difference is 0.72 standard deviations. Our pilot RCT using the original REACH VN showed effect sizes of at least 0.9, so the current study is powered to detect smaller effects, which might be expected in a telehealth administration of the intervention.