

Official title: Randomized Trial of a Technology-based Positive Emotion Intervention for Informal Caregivers of Individuals With Alzheimer's Disease

Brief title: Life Enhancing Activities for Family Caregivers (LEAF 2.0)

NCT#: NCT03610698

Date: 10/20/2025

Demographic characteristics, including age, gender, race, ethnicity, income, education, and residence were summarized for the sample as a whole, and by intervention group (Facilitated Intervention, Self-Guided Intervention, and combined Control). Differences between groups were calculated using one-way ANOVA for continuous variables and Chi-squared tests for categorical variables; Fisher's exact tests were used when required by the distribution. Baseline scores for each outcome were compared across the three groups using ANOVA and Kruskal-Wallis tests, depending on the distribution of the data.

Change over time and differences within- and between- intervention groups were assessed using mixed effects linear regression models. Time (baseline, post-intervention, follow-up 1 and follow-up 2) was treated categorically to allow for slope estimates to differ between consecutive timepoints. Models included a random effect for intercept and time. From these models, within-group and between-group differences across intervention groups (Facilitated, Self-Guided, and Control) were estimated between baseline and each follow-up time point (post, FU1, and FU2) using least square means estimates. Effect sizes were calculated to compare change over time across intervention groups.

Lastly, we calculated the number of sessions/weeks completed for each participant during their intervention period to assess how the number of weeks completed moderate the effect of intervention on change in each outcome. We used mixed effects linear regression models including time, intervention group, and usage (none, some, or all sessions) to estimate the change from baseline to each follow-up (post, FU1, and FU2) in both intervention groups, and test for significant change both within and across intervention groups (facilitated, self-guided).

All analyses were performed using SAS v. 9.4; p-values were considered significant at $p < 0.05$.