

**Title: Social-LEAF Life Enhancing Activities for Caregivers**

**NCT05274074**

**Date: 1.9.25**

Analysis will be intent to treat. We will examine balance of demographic and outcome measures across groups at baseline using chi-square tests for categorical variables and t-tests for continuous variables. For cell frequencies less than 5 fisher's exact test will be used and for continuous variables with heavy skew Kruskal Wallis tests will be used.

The primary analysis assessing intervention effects will be conducted with general linear models comparing the change from baseline to the week 6 visit by group. Model specification will include change from baseline to week 6 for each measure as the outcome and group as the independent variable. Within group change will be estimated as least squares means with corresponding 95% confidence intervals.

PROMIS instruments administered via a computer adaptive test will be analyzed on the T-score metric provided by the computer adaptive testing administration. Those scores are normed on a national sample, in which they have a mean of 50 and standard deviation (SD) of 10. For the remaining instruments including the primary outcome PROMIS Positive Affect, raw scale scores will be analyzed. Differences between the change from baseline and the week 6 visit in each group will describe effect sizes. Higher scores indicate higher values of the construct being measured by the instrument (i.e. higher PSS scores indicate higher stress, higher PROMIS depression scores indicate higher depression).

Statistical tests will be 2-sided F-tests with an alpha of .05 comparing the intervention and waitlist control on change from baseline to week 6 for each outcome. All analyses will be based on actual data and no imputation of missing data will be performed. Given the small sample size, lack of power, and preliminary nature of the study, no formal adjustments will be made for multiple comparisons.