VOCALE LBD+ for Caregivers of Persons With Lewy Body Dementia NCT05622734

August 27th, 2024

Study Design

This study was a pilot quasi-experimental single-arm study to examine preliminary effects of the VOCALE LBD+ intervention. Primary outcome measures were collected at the beginning and end of the eight-week intervention

Recruitment and Participants

Participants were primarily recruited from the Memory and Brain Wellness Center (MBWC) at Harborview Medical Center in Seattle, Washington. The MBWC evaluates over 1000 new patients annually and is the only major academic medical center in the five-state region of Washington, Wyoming, Alaska, Montana, and Idaho. Participants were also recruited through posted announcements on the websites and newsletters of community organizations such as Lewy Body Disease Association (LBDA) and Alzheimer.gov that serve the target population.

To be <u>eligible</u> for participation, persons should be a family/informal caregiver of a person with a diagnosis of LBD; can read, write, and speak English; has a device that can access the Internet and be used for videoconferencing and/or phone calls; is 18 years or older.

Primary Outcome

Seven-item Pearlin Mastery Scale was used to measure mastery. On a scale of 1 to 4 (with 1 being "strongly disagree" and 4 being "strongly agree"), the measure assessed how strongly do you agree or disagree. Items 1 through item 5 were reversed so scores range from 7 to 28 and higher scores indicate greater mastery.

Analysis Plan

Data were analyzed across time points using Cohen's d to quantify effect sizes, focusing on changes from baseline to the end of the intervention. To address potential data non-normality and provide robust estimates, we employed bootstrapping with 1,000 resamples using the boot package in R to determine the 95% confidence intervals of the effect sizes.