

Date: 7/14/2024

Title of Study: EMPOWER PD

Identifier: NCT05640167

Study Protocol

Participants were consented and enrolled at the first clinic appointment and received a comprehensive assessment by each member of an interdisciplinary team, including physical therapy, speech therapy, nutrition, and pharmacy and completed demographic and baseline characteristics such as age, sex, ethnicity, race, years living with PD and stage of disease, education and cognitive status as measured by the Montreal Cognitive Assessment (MoCA). Participants returned the following week for a half day educational symposium which was a group format and included a session from each of the disciplines on topics such as exercise, nutrition, communication, socialization, and medication management. The final clinic session was a one hour 1:1 meeting with individualized recommendations provided and goals set. A participant-identified caregiver was allowed to accompany the participant throughout the assessment and educational process whenever possible, but no information was collected from them.

Statistical Analysis

Descriptive data are presented as means (SD). Data was assessed for normality using skewness (<3) and kurtosis (<10). All data were normally distributed; therefore, no transformations were necessary prior to analysis. Of the 3 intervention sessions, there were missing data files for the due to cognitive impairment of one participant and therefore that participants data is only included in completed surveys and self-report measures.

Survey data was analyzed from the collected responses from participants regarding their agreement with 12 statements on a 5-point Likert scale. The average percentage of agreement for each statement was calculated by taking the mean of responses, resulting in an overall agreement score ranging from strongly disagree (0 %) to strongly agree (100%). Additional self-report measures using Likert scales

To investigate the impact of the clinic on education and other self-report measures two-tailed t-tests were completed on data (education: PDKQ and Hei-Q; self-report measures: ABC, SEE, and PFS-16) with significance $< .05$. Using G-power (Faul 2009) an estimated 26 participants were required to reach .80 power and .5 effect. It is important to note that this is a pilot study; therefore, it was not designed or powered to detect statistically significant differences between groups. Thus, all findings are considered preliminary. Data were analyzed using the data analysis package in Excel v.16.86.

Consent

This study was approved by the University of Rhode Island's Institution Review Board # 1929810-2. Written consent was obtained from all participants in the study.

