O0958-M

Treatment of Emotional Prosodic Disorders in Parkinson's Disease

NCT01956266

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Statistical Analysis Plan

Power analysis A sample power analysis using G*power (Erdfelder et al., 1996), and using an effect size from this treatment protocol in stroke with an alpha level of .05, power of .80, 1 group, indicated that we needed to recruit at least 24 participants to detect a small to medium effect size. As mentioned above, there is currently no data on means or standard deviations for these treatments within a Parkinson's disease population.

We propose to recruit approximately 24 participants for during the span of the CDA1 to serve as pilot data for treatment feasibility, treatment effect, and test-retest reliability for the primary outcome measure. Of this 24, we expect approximately half to receive treatment and half to participate only in test-retest reliability testing. The resulting data will be used for a power analysis based on means and standard deviations in PD to provide the number of subjects we will need to treat in subsequent studies.

Primary outcome measure - determine treatment effect size by comparing changes in acoustic variability. Affective sentence production. A list of 96 semantically neutral sentences of between five to seven words, spoken in one of four emotional tones of voice (24 each of happy, sad, angry and fear), presented in randomized order, will be administered before initiating treatment, after treatment is commenced, and at one month post treatment commencement. All sentences will be rated acoustically and perceptually. Repeated measures ANOVAS (or nonparametric equivalents) will be used to compare on the primary measure of acoustic variability: (a) pitch of frequency variability, and (b) intensity or loudness. If measurement time is a significant predictor of Fo range at a .05 Type I error level, we will use Tukey's method for pairwise comparisons to maintain the Type I error at .05 while performing post-hoc t-tests to determine which time point means are significantly different. As a secondary manner of analyzing this data if acoustic measures do seem not seem to have adequately captured any change, the prosodic expression outcome measure will also be perceptually rated offline by three trained judges who will rate the type of prosody and the intensity of emotional expression (0-5). The blinded judges for these and subsequent evaluations will be trained in evaluating the prosody of emotionally intoned sentences. Training for these judges will include familiarization with the descriptions of features for each emotion with respect to changes in pitch, loudness, and rate. Both intra- and inter-judge reliability will be calculated for these blinded judges.

Secondary outcome. Performance on identification, discrimination, and naming of facial and prosodic expressions of emotion. These will be assessed using the FAB before and right after treatment. Paired samples t-tests were used to compare performance on standardized tasks of affect recognition before and immediately following treatment.

Intra- and Inter-Judge Reliability. To evaluate intra-judge (test-retest) reliability, we will calculate mean and standard deviation of differences in the three perceptual outcome measures between the first and the second administration. Furthermore, we will calculate an intraclass correlation coefficient (ICC) estimate as well as a 95% confidence interval for ICC. In addition, ICC and related 95% confidence interval will also be calculated for inter-judge reliability at the first and the second administration, separately