Home-based Transcranial Direct Current Stimulation for Pain Management in Persons with Alzheimer's Disease and Related Dementias

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Statistical Analysis Plan (SAP)

A standard randomized controlled design will be adopted in this study, and we will randomly assign 40 patients to either active tDCS or sham tDCS (20 per group). Our primary analysis will compare clinical pain changes from baseline to the final intervention session between the active tDCS and sham tDCS groups. We plan to conduct 2 hypothesis tests for the main outcomes (MOBID-2 and fNIRS at Day 5) at a family-wise significance level of $\alpha = 0.025$ after Bonferroni correction. With the sample size 20 per group, we will be able to detect the expected effect size of 1.0 with 80% power at a significance level of 0.025.

All data will be analyzed using the intention-to-treat approach. All demographic and clinical variables will be summarized using descriptive statistics, such as mean ± standard deviation or median (interquartile range) as appropriate for continuous variables and frequency and percentage for categorical variables. The distribution of all variables will be examined to check the validity of distribution assumptions before any analysis, using measures of central tendency and a visual inspection of histograms and quantile-quantile plots. If the assumption of normality is not met, nonparametric approaches will be employed. SAS 9.4 (SAS Institute, Cary, NC) will be used to perform the proposed statistical analyses.