

Title: The Effects of Repetitive Transcranial Magnetic Stimulation Prefrontal Target Location on Outcomes for Major Depressive Disorder

ID: 201709834

Date: 08/22/2019

rTMS Clinical Database (IRB ID#201709834)  
Data Analysis Plan

We will compare pre- and post-treatment rating scales, cognitive scores, and EEG/MRI results. Rating scales and cognitive/neurobehavioral scores will be analyzed using hypothesis-driven t-tests. iPad cognitive testing is normed to a US population adult control and results will be analyzed as T-statistics comparing the patients against a general population sample. A comparison of mean changes with confidence intervals and standard deviation calculations will be analyzed, as well as the difference in remission and response rates to treatment. For MRI we will compare structural volumetric changes, functional connectivity changes, T1rho pH changes, and DTI anisotropy changes.

Analysis pipeline is well established as mentioned above, with R package RnBeads and Minfi. We will control for standard demographics, including age, sex, race and psychotropic medication use known to affect DNA methylation status.

Audio recordings and their transcription are analyzed using a machine-learning algorithm to evaluate the predictive quality of vocal pattern detection and content value for treatment response to TMS.

Data received from IRB#201810778 will be used as a comparison group for this study's heart rate variability data. Mean differences will be compared with t test statistics.

Based on previous work showing small efficacy differences between targets (31% remission with 5cm rule vs. 35% remission with certain Brodmann area targeting), power analysis with desired power of 0.80 and alpha of 0.05, we would need approximately 88 patients (44 in each group). We propose to recruit 200 patients.