Treating Stimulant Addiction With Repetitive Transcranial Magnetic Stimulation (rTMS)

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Hypothesis Testing

Primary Outcome Hypothesis: Compared to sham treated subjects, active rTMS treated subjects will show lower relapse rates. Treatment groups will be compared on their rates of relapse using Chi-square tests.

We will conduct an intent to treat (ITT) analysis for hypothesis testing. We will supplement this analysis with a per protocol analysis in which only subjects who completed all rTMS treatments will be compared. We will include an examination of whether bias has been introduced due to dropout by determining if there is greater dropout in the treatment group, and if significant differences exist in major demographic and clinical variables of individuals who have dropped out compared to those who have not. We will correct for any significant differences using covariates in our statistical models.

Our study design includes randomization to minimize selection bias. However, to address the possibility of residual confounding, we will conduct the following post-randomization analysis. We will compare the baseline characteristics of the treatment groups to identify any imbalance in demographic or other characteristics that could be confounding group comparisons. These include age, level of use of stimulants, gender, presence of and/or severity of psychiatric co-morbidity, and level of functional impairment. If imbalances are detected, we will use regression models adjusting for these variables to isolate the effect of the treatment.