Repetitive Transcranial Magnetic Stimulation for Dementia

Statistical Analysis Plan

NCT02621424

January 31, 2020

RTMS for Dementia Statistical analyses Plan:

Primary Hypothesis 1 (Primary Memory Outcome): rTMS will lead to higher performance on the California Verbal Learning Test (CVLT-II) compared to performance by participants in the sham treatment group at the termination of treatment.

Secondary Hypothesis 2 (Secondary Cognitive Outcomes): rTMS- will lead to higher performance on secondary cognitive measures relating to language (Animal Fluency and Boston Naming Test, BNT), visual memory (Brief Visual Memory Test, BVMT) and executive functioning and processing speed (Trail making A&B), compared to performance by participants in the sham treatment group at the termination of treatment.

Secondary Hypothesis 3 (Exploration of Mechanism of Action): rTMS-induced memory improvement parallels changes in BDNF levels after treatment.

Mixed model analysis will be used to compare performance on the primary neuropsychological measures (CVLT-II Long-Delay Free Recall and Cued Recall and CVLT Short-Delay Free Recall and Cued Recall) by the treatment and control group at the cessation of treatment and at 4 months after cessation of treatment. Secondary analyses will also be conducted to compare performance between the groups at the same time points on Animal Fluency, Boston Naming Test, Brief Visual Memory Test (BVMT) and Trail making A&B.

We expect that changes in BDNF measures relating to neuronal plasticity over the course of treatment may account for some of the observed effects of rTMS on memory. Therefore, mixed model analysis will also be used to compare BDNF levels at baseline and after the RTMS treatment.