2.4 to 5.3 11-13. Higher baseline scores require larger raw changes to represent clinically important differences 14. Primary aim: To determine efficacy of intranasal ketamine in reducing cancer related pain. A clinical trial will be conducted to determine effect of intranasal ketamine on cancer related pain. Pain scores will be recorded on Numerical Pain Rating Scale (NPRS) at regular intervals throughout the study. Minimal clinically important differences (MCIDs) for pain ratings varies substantially based on patient population and statistical technique used, range of 0.4 to 3.7 points has been reported as a MCID. In general, improvements of pain severity < = 1.5 points on NPRS could be seen as clinically irrelevant 9-13. Above that value, the cutoff point for “clinical relevance” depends on patients’ baseline pain severity, and ranges from 2.4 to 5.3 11-13. Higher baseline scores require larger raw changes to represent clinically important differences 14. Several clinical trials for pain have reported a reduction of 2 points on NPRS to be clinically important.15-17 Therefore for the purposes of this study, MCID of 2 was used for sample size calculations. A prior research study done by Carr et al. studied effects of intranasal ketamine for breakthrough pain in patients with chronic pain of various etiologies. 18 Total number of subjects in this study was 20 (4 of these had cancer related pain). This study demonstrated a mean reduction of 2.7 units on NPRS (P < 0.0001), with standard deviation of 1.87. Since MCID is 2, effect size using this (MCID/SD) = 1.05. Power and sample size table: Assumptions: 1. T-test is the appropriate test (may not be the appropriate test since we have a small sample size and may not be able to assume normality of means based on the central limit theorem) 2. Distribution of reductions in pain score is normal. 3. Effect size of 1.05 is clinically meaningful; Sample Size: A sample size of 7 from a population of 20 (in the study done by Carr et al.) achieves 80% power to detect a NPRS difference of ~ 2 between the null hypothesis mean of 0.0 and the alternative hypothesis mean of 2 with an estimated standard deviation (SD) of 1.87 and with a significance level (alpha) of 0.05 using paired t-test assuming that the actual distribution is normal. We will include 10 patients to account for the possibility that the observed pain reduction in the current study may be different than the study done by Carr, as in this study patients were given ketamine for breakthrough pain, as opposed to for baseline pain. We will enroll 25 patients in the study to account for potential dropouts. RESULTS/ANTICIPATED RESULTS: Majority of subjects experienced the largest decrease in their pain with the 10mg IV dose. Side effects included nausea/vomiting and a feeling of unreality. All side effects resolved by the end of each study visit. No severe adverse events occurred. DISCUSSION/SIGNIFICANCE OF IMPACT: Further study is required to elucidate safety of NAS ketamine with long term use for cancer related pain.

Effects of non-invasive brain stimulation on speech fluency and brain activity in adults who stutter: a randomized controlled clinical trial

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OBJECTIVES/SPECIFIC AIMS: The goal of this study is to measure speech fluency and brain activity before and after 5 days of behavioral speech fluency training alone (sham group) or speech training plus stimulation (active group). A 1-month follow-up will also be completed. The first primary outcome measure is changes in brain activation in speech motor control/timing network. The second primary outcome measure is changes in percentage of stuttered syllables during speech sample (speech fluency). The secondary outcome measure is changes from baseline on the Overall Assessment of Speakers Experience of Stuttering (OASES), a detailed subject rating of how stuttering affects their lives. METHODS/STUDY POPULATION: This study is a between subjects, counterbalanced, sham-controlled, double-blind design. Participants will be 40 adults who stutter who will be randomized (using minimization) into either the active or