

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.

3178

Effects of Motor Skill Training vs. Strength and Flexibility Exercise on Functional Limitations, Pain, and Movement Characteristics in People with Chronic Low Back Pain

Quenten L Hooker¹, Kristen Roles¹, Vanessa M. Lanier¹ and Linda R. Van Dillen¹

¹Washington University in St. Louis

OBJECTIVES/SPECIFIC AIMS: Compare the short- and long-term effects of 2 treatments, MST and SF, on limitations in function, pain, and movement characteristics. The movement characteristics included the amount of early excursion (1st half of decent) of the knee, hip, and lumbar spine during a functional activity test of

picking up an object. METHODS/STUDY POPULATION: 154 participants were randomized to 6, 1-hour treatment sessions (once/week for 6 weeks) of MST or SF. The MST group received individualized training to modify pain-provoking altered movement patterns during functional activities. The SF group received exercises for trunk strength and trunk and limb flexibility. At baseline, post-treatment and 6-month follow-up participants completed the modified Oswestry Disability Questionnaire (MODQ, a functional limitation measure; 0-100%), the Numeric Pain Rating Scale (NRS, average pain prior 7 days; 0-10) and a standardized pick up an object test, where sagittal plane knee, hip and lumbar spine excursion were calculated using 3D motion capture. A mixed model repeated measures ANOVA was used to examine the following effects: Treatment group (Tx), Time and Tx X Time for each self-report and movement variable. When the ANOVA was significant ($p < 0.05$), a priori planned contrasts were examined. RESULTS/ANTICIPATED RESULTS: There was a significant Tx X Time interaction ($p < 0.01$) for each outcome. Baseline: MST and SF were similar in MODQ scores [Δ 0.4% (-3.4 - 2.9)], NRS [Δ 0.0 (-0.6 - 0.6)], knee [Δ 2.2° (-6.7 - 2.5)], hip [Δ 0.4° (-2.9 - 2.5)], and lumbar spine [Δ 0.1° (-1.4 - 1.2)] early excursion. Post-Treatment: Both group's MODQ and NRS scores decreased ($p < 0.01$), but MST had a greater reduction in MODQ scores [Δ -7.6% (-3.9 - -11.0)] and lower average NRS scores [Δ -0.8 (-0.1 - -1.4)] compared to SF. MST changed knee [Δ +18.6° (14.6 - 22.1)], hip [Δ +10.8° (8.5 - 13.1)], and lumbar spine [Δ -2.0° (-3.0 - -1.0)] early excursion, while SF did not change early joint excursion (all $p > 0.72$). 6-Month Follow-up: The differences between MST and SF were maintained for all outcomes ($p > 0.26$). DISCUSSION/SIGNIFICANCE OF IMPACT: MST was more effective at reducing functional limitations and pain and improving movement patterns during a functional activity compared to SF. For all variables, the differences identified during treatment between MST and SF were maintained at 6-month follow-up. Therefore compared to SF, MST that targets performance of altered movement patterns during functional activities appears to be superior for attaining and maintaining changes in functional limitations, pain, and movement characteristics in people with CLBP.

3010

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

Emily O'Dell Garnett, Ph.D., CCC-SLP¹, Soo-Eun Chang, Benjamin Hampstead¹ and Ho Ming Chow¹

¹University of Michigan School of Medicine

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