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## **A Multi-Site Randomized Control Study for the Use of Cortical Stimulation and Occupational Therapy**

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### **Introduction:**

This multi-disciplinary study investigates a neurosurgical intervention combined with an occupation-based upper limb rehabilitation protocol. It is based upon animal model research that demonstrates successful use of cortical stimulation to ameliorate upper limb hemiparesis. This study incorporates the task-oriented approach into the treatment protocol.

### **Objectives:**

This study is a multicenter, randomized trial to determine if cortical stimulation therapy delivered concurrent with occupation based treatment will enhance upper extremity motor recovery in chronic stroke patients.

### **Methods:**

Subjects are randomized to one of two study arms: 1) Investigational treatment group- receives a cortical stimulation implant followed by a 6 week occupational therapy treatment protocol. 2) Control treatment group- does not receive a cortical stimulation implant but instead receives the same 6 week treatment protocol as the investigational group. The six week occupational therapy protocol includes 2.5 hours of rehab 5 times per week for four weeks. The session frequency is reduced to 3 times per week the last two weeks. The daily sessions include an initial session focusing on manipulation activities tailored to individual subjects, followed by a rest break, followed by a second session focused on basic ADLs and client identified occupations from the COPM. Measurement data is collected throughout the six month follow-up period at week 1, 4, 8, 12 and 24. The FDA and participating site IRBs approved this study.

### **Results:**

153 patients have been randomized. Results indicate that both treatment groups demonstrate improvements in function/performance with ADL's as determined through standardized measures. 4-week follow-up results indicate 29.1 % improvement in therapy only (control) group.

### **Conclusion:**

Use of this task-oriented occupational therapy treatment protocol may benefit persons with upper extremity motor hemiparesis as a result of a stroke.

### **Contribution to the practice/evidence base of occupational therapy:**

This study is the largest randomized rehabilitation study to date studying the effect of cortical stimulation to stroke rehabilitation outcomes. It will also serve as a useful guide to future researchers who are interested in developing well controlled rehabilitation studies. The use of the occupational therapy protocol supports the relevance of a task-oriented, occupation-based approach to rehabilitation.