

TESTING THE EFFECTS OF MULTISITE TRANSCRANIAL MAGNETIC STIMULATION ON TOURETTE SYNDROME

STUDY SEEKS LONGER-TERM BENEFITS FROM TOURETTE TREATMENT

Tourette syndrome (TS) is a neurodevelopmental condition that affects nearly 1 percent of children worldwide. While it can be treated with drugs and behavioral therapy, other modalities are being sought, especially in cases that are resistant to standard treatment. Keith Coffman, MD, Director of Tourette Syndrome Center of Excellence at Children's Mercy Kansas City, is leading the way with a study designed to better understand the long-term effectiveness of multisite transcranial magnetic stimulation (mTMS).

TMS is already FDA-approved for treatment of depression and obsessive-compulsive disorder. It's also used in various clinical studies to better understand its effectiveness in controlling Tourette syndrome symptoms. In these studies, magnetic stimulation is performed using a hand-held device that is bulky, delivers a high level of current that can cause unpleasant sensations, and can provide stimulation at only one cortical site at a time. Some studies using this device have shown promising results, but the benefits have worn off because patients were unable to keep a regular schedule of hospital visits for access to the device.

THE EVOLUTION OF TECHNOLOGY

A new portable device has been developed and patented by Dr. Santosh Helekar of Houston Methodist Research Institute (HMRI) and Dr. Henning Voss of Weill Cornell Medical College (WCMC). The only device of its kind in the U.S., it's smaller and wearable and can deliver stimuli at multiple cortical sites simultaneously or sequentially.

It uses rapidly rotating, small, high-strength permanent magnets to induce currents in the brain. This device delivers lower levels of current during stimulation, eliminating the discomfort common with other TMS devices. Best of all, it can be used at home, making it more practical. This device is the cornerstone of Dr. Coffman's study.



Portable TMS device that delivers stimuli at multiple cortical sites.

SETTING GOALS FOR THE STUDY

Dr. Coffman's study is testing the therapeutic effectiveness of bilateral mTMS of the supplementary motor areas (mTMS-SMA therapy) in TS patients presenting with tics uncontrolled by standard drug and behavioral treatment.

Two types of devices will be used: One is real and the other is a sham device. Only the manufacturer knows the difference. Patients are randomized at enrollment in a placebo-controlled fashion.

The specific aims of this study are:

1. To compare the immediate benefits experienced by TS patients subjected to stimulation to the TS patients receiving placebo treatment, in terms of reduction of the frequency of tics and alleviation (primary end points) of other comorbidities (ADHD and OCD, secondary end points) of TS.
2. To compare the long-term benefits over a two-month follow-up period in the same set of treated and placebo control TS patients.

CRITERIA FOR PARTICIPATION

To be considered for the study, a patient must meet these criteria:

- Meet a specific threshold on the Yale Global Tic Severity Scale (YGTSS) in order to show a drop in baseline level of symptoms.
- Cannot have epilepsy, due to seizure risk from stimulation.
- No implanted devices in body, such as vagal nerve stimulator, cochlear implants or intracranial hardware.

Children's Mercy Kansas City is the only exclusively pediatric Tourette Center of Excellence in the U.S., as designated by the Tourette Association of America.

STUDY DESIGN

- The study period is 10 days, with five consecutive days of mTMS per week for two weeks.
- Each session lasts one hour.
- Symptom levels are assessed at enrollment and periodically during the treatment.
- Patients are assessed again at follow-up visits two weeks and one month post-treatment.
- Patients are also assessed for changes in levels of anxiety, ADHD symptoms and obsessive-compulsive symptoms.

RESULTS

Dr. Coffman and his team are enrolling patients currently. Study details are listed on clinicaltrials.gov, where providers and patients' families can find enrollment details. Once the entire cohort has been enrolled and treated, results will be available several months later.



LEARN MORE ABOUT mTMS FOR TOURETTE SYNDROME.

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