Transcranial Magnetic Stimulation for Attention Deficit/Hyperactivity Disorder (ADHD)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03663179

Recruitment Status: Recruiting
First Posted: September 10, 2018
Last Update Posted: September 10, 2018

See Contacts and Locations

Sponsor:
University of Pennsylvania

Information provided by (Responsible Party):
University of Pennsylvania

Study Description

Brief Summary:
This study will test the effects of transcranial magnetic stimulation (TMS) on clinical measures of ADHD symptoms.

Detailed Description:
Attention Deficit Hyperactivity Disorder (ADHD) is characterized by symptoms of impulsivity, inattention, and hyperactivity that emerge in childhood and frequently persist into adulthood. These symptoms are accompanied by deficits in cognitive control and risky decision making that can lead to negative psychosocial and health-related outcomes. With advances in the neuroimaging field, researchers are learning where and how self-control over decisions and behaviors is executed in the brain. This work points to the central role of neural activity in the dorsolateral prefrontal cortices (DLPFC) in self-control processes that contribute to healthy choices. Emerging evidence shows that activity in the prefrontal cortices and cognitive control circuits can be modulated using a noninvasive and safe intervention: repetitive TMS. This within-subject proof of concept study will investigate whether 20 sessions of TMS (versus sham stimulation) can enhance executive cognitive function in adults with ADHD.

Study Design

Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 95 participants
Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Triple (Participant, Care Provider, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: A Pilot Study of Repetitive Transcranial Magnetic Stimulation for Adult ADHD

Actual Study Start Date: January 2017

Estimated Primary Completion Date: December 2018

Estimated Study Completion Date: June 2019

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

U.S. FDA Resources

Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Active TMS</td>
<td>Device: Transcranial Magnetic Stimulation (TMS)</td>
</tr>
<tr>
<td>Participants will receive</td>
<td>A MagPro R30 (Magventure, Inc., Copenhagen, Denmark) device with a Cool-B65 A/P figure 8 coil will be used to deliver TMS. This coil has an active side and a sham side, and can be used to perform double-blinded studies. TMS will be administered at 10 Hertz (Hz) with an intensity of 120% of patient resting motor threshold. Stimulation will be delivered to the left dorsolateral prefrontal cortex using 20 sec cycles (i.e., 5 sec train with 15 sec inter train interval). Subjects will receive 80 trains per session for a total of 4000 pulses per session (~26 min sessions). Twenty sessions will be completed on sequential weekdays (5 days per week for 4 weeks).</td>
</tr>
<tr>
<td>Participants will receive</td>
<td>20 sessions of active TMS targeting the left DLPFC.</td>
</tr>
<tr>
<td>Sham Comparator: Sham TMS</td>
<td>Device: Sham Transcranial Magnetic Stimulation (Sham TMS)</td>
</tr>
<tr>
<td>Participants will receive</td>
<td>A MagPro R30 (Magventure, Inc., Copenhagen, Denmark) device with a Cool-B65 A/P figure 8 coil will be used to deliver TMS. This coil has an active side and a sham side, and can be used to perform double-blinded studies. For sham stimulation, the sham side of the coil is positioned toward the participant's scalp. The sham coil is designed to mimic the appearance and sound of active TMS stimulation, but is equipped with a magnetic shield that reduces the strength of the field by approximately 80%. This reduction in field strength ensures that no neural stimulation occurs. Twenty sessions will be completed on sequential weekdays (5 days per week for 4 weeks).</td>
</tr>
<tr>
<td>20 sessions of sham TMS over the</td>
<td></td>
</tr>
<tr>
<td>left DLPFC.</td>
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Outcome Measures

Primary Outcome Measures:

ADHD symptoms will be assessed using the well-validated Conners Adult ADHD Rating Scale - Self-Report: Long Version (CAARS-S:L). The CAARS-S:L is a 66-item rating scale designed to assess ADHD symptoms in adults. The scale contains multiple subscales to assess Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV) specified ADHD criteria as well as other facets of ADHD such as inattention/memory problems, hyperactivity/restlessness, impulsivity/emotionality, and problems with self-concept. Subscale results are converted to T-scores (range: 25-90), where 50 is the standardized population mean and every 10 points indicates one standard deviation from the mean. Higher values generally indicate more difficulties with ADHD symptoms. This measure will be administered at baseline at the end of 4 weeks of treatment. The primary outcome will be the change from baseline to week 4.

Secondary Outcome Measures:

1. Change in performance on Conners Continuous Performance Task (sustained attention)  
   [ Time Frame: Week 4 ]

The Conners Continuous Performance Task (Conners CPT) will be administered at baseline and weekly during the treatment period to assess sustained attention. In this task, participants are shown a series of stimuli (letters, numbers, or pictures) on a computer screen and are asked to press the spacebar in response to certain stimuli, but to withhold responding to other stimuli. The Conners CPT produces several measures of performance including percentage of false positive responses and variability in response times. This measure will be administered at baseline at the end of 4 weeks of treatment. The secondary outcome will be the change from baseline to week 4.

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 18 Years to 65 Years  (Adult, Older Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Eligible participants will be:

1. Healthy males and females who are between 18 and 65 years of age with an ADHD diagnosis (meet diagnostic criteria for ADHD on the SCID-5 module for adult ADHD);
2. Planning to live in the area for at least the next 6 weeks;
3. Capable of giving written informed consent, which includes compliance with the requirements and restrictions listed in the combined consent and HIPAA form;
4. Able to communicate fluently in English (speaking, writing, and reading).

Exclusion Criteria:
Subjects who present and/or self-report with the following criteria at any point during study participation will not be eligible to participate in the study:

**Alcohol/Drugs:**

1. History or current diagnosis or treatment for alcohol or drug abuse (as reported during phone screen);
2. Positive breath alcohol concentration test (BrAC greater than or equal to 0.01) at intake;
3. A positive urine drug screen for cocaine, phencyclidine (PCP), amphetamines, methamphetamines, benzodiazepines, methadone, and/or barbiturates at Intake, Baseline, or Sessions 5, 10, 15 or 20.

**Medication:**

Current use or recent discontinuation (within the past 6 months at the time of Intake) of:

1. Gamma-Aminobutyric Acid (GABA)-ergic medications
2. Glutamatergic medications
3. Any medication for the treatment of ADHD
4. Benzodiazepines
5. Any medication that is known to lower the seizure threshold (e.g., clozapine, bupropion, tramadol, carabapemems, stimulants)
6. Any medication that could compromise participant safety as determined by the Principal Investigator and/or Study Physician

Current use or recent discontinuation (within the last 14 days at the time of Intake) of:

7. Anti-psychotic medications
8. Nicotine replacement therapy (NRT)

Daily use of:

9. Opiate-containing medications for chronic pain

**Medical/Neuropsychiatric:**

1. Women who are pregnant, planning a pregnancy, and/or breast feeding.
2. History of seizures, epilepsy, or history of epilepsy in first-degree relative
3. History of stroke or transient ischemic attack (warning stroke)
4. History of traumatic brain injury or self-report of brain or spinal tumor
5. History of head injury with unconsciousness lasting more than 5 minutes
6. Previous brain surgery
7. Any additional neurological condition that would likely reduce the safety of study participation, including central nervous system (CNS) vasculitis, intracranial tumor, intracranial aneurysm, multiple sclerosis or arteriovenous malformations
8. History of tinnitus
9. History of diabetes mellitus
10. History of atherosclerotic vascular disease
11. A medically unstable cardiopulmonary or metabolic disorder
12. Increased risk for myocardial infarction or other major cardiopulmonary complications.
13. Any uncorrected visual impairment or abnormality
14. Self-reported history, current diagnosis of psychosis or symptoms consistent with a mood disorder based upon the Structured Clinical Interview for DSM-5 (SCID), including schizophrenia, mania, bipolar disorder, an eating disorder, obsessive compulsive disorder, an anxiety disorder, major depression (subjects with a history of major depression but in remission for past 6 months are eligible).

**TMS-related:**
1. Subjects with ferromagnetic material in or in close proximity to the head (with the exception of oral
dental devices)
2. Implanted devices (including vagus nerve stimulator (VNS), deep brain stimulator (DBS),
pacemakers, spinal cord stimulators, medication pumps, ventriculo peritoneal shunts, defibrillators,
intracardiac lines)
3. Self-report of any skull fracture or opening
4. A disturbance in normal sleep patterns/sleep deprivation

General Exclusion:
1. Any medical condition, illness, disorder, or concomitant medication that could compromise
participant safety or treatment, or affect clinical or cognitive outcomes, as determined by the
Principal Investigator
2. Inability to complete study tasks and provide quality data, as determined by the Principal
Investigator
3. Low or borderline intellectual functioning - determined by a score of less than 90 on the Shipley
Institute of Living Scale (SILS) (administered at Intake Visit). The SILS correlates with the Wechsler
Adult Intelligence Scale-Revised (WAIS-R) Estimated Intelligence Quotient (IQ) Test
4. Inability to provide informed consent

Contacts and Locations
Go to  ▼

Information from the National Library of Medicine
To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.
Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03663179

Contacts
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    Sub-Investigator: Roy Hamilton, MD
    Sub-Investigator: J. Russell Ramsay, PhD

Sponsors and Collaborators
University of Pennsylvania

Investigators
Principal Investigator: Caryn Lerman, PhD  University of Pennsylvania

More Information
Go to  ▼
**Additional Information:**
Website with information for those interested in participating in the study.

**Responsible Party:** University of Pennsylvania

**ClinicalTrials.gov Identifier:** NCT03663179  
**History of Changes**

**Other Study ID Numbers:** 826586

**First Posted:** September 10, 2018  
**Key Record Dates**

**Last Update Posted:** September 10, 2018

**Last Verified:** August 2018

**Individual Participant Data (IPD) Sharing Statement:**

**Plan to Share IPD:** No

**Studies a U.S. FDA-regulated Drug Product:** No

**Studies a U.S. FDA-regulated Device Product:** Yes

**Device Product Not Approved or Cleared by U.S. FDA:** No

**Pediatric Postmarket Surveillance of a Device Product:** No

**Keywords provided by University of Pennsylvania:**
ADHD
TMS

**Additional relevant MeSH terms:**
Attention Deficit Disorder with Hyperactivity  
Dyskinesias
Hyperkinesis  
Neurologic Manifestations
Attention Deficit and Disruptive Behavior Disorders  
Nervous System Diseases
Neurodevelopmental Disorders  
Signs and Symptoms
Mental Disorders