Purpose

The purpose of this study is to see if a non-medication intervention can increase motivation in individuals with ADHD by observing brain activity using magnetic resonance imaging (MRI).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>ADHD</td>
<td>Other: Real-Time functional Magnetic Resonance Imaging Feedback (RTFF)</td>
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</tbody>
</table>

Study Type: Interventional

Study Design: Intervention Model: Single Group Assignment
Masking: Open Label

Official Title: Increasing Motivation in Attention Deficit Hyperactivity Disorder (ADHD) Via Self-activation of Ventral Tegmental Area (VTA)

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
Further study details as provided by Duke University:

Primary Outcome Measures:

- Percent signal change in VTA BOLD activation [Time Frame: experiment session 1, approximately 1 hour] [Designated as safety issue: No]
  The investigators will examine the % signal change in VTA BOLD activation during "Activate" versus "Count" trials during the Pre-Test run on experimental session 1, prior to RTFF training.

- Change in VTA BOLD signal following RTFF [Time Frame: Baseline and following real time fMRI feedback, up to 2 weeks] [Designated as safety issue: No]
  Four imaging task sessions will be done 24-72 hours apart

Secondary Outcome Measures:

- Change in goal-directed behavior, as measured by the Paced Auditory Serial Addition Task (PASAT) [Time Frame: Baseline and following each of the RTFF sessions, up to 2 weeks] [Designated as safety issue: No]
  The amount of time before the participant terminates will assess their willingness to persist in goal-directed behavior. Four task sessions will be done 24-72 hours apart

- Change in goal-directed behavior, as measured by the Effort discounting task [Time Frame: Baseline and following each of the RTFF sessions, up to 2 weeks] [Designated as safety issue: No]
  The amount of time before the participant terminates will assess their willingness to persist in goal-directed behavior. Four task sessions will be done 24-72 hours apart

- Change in working memory, as measured by accuracy on a modified version of the n-back task [Time Frame: Baseline and following each of the RTFF sessions, up to 2 weeks] [Designated as safety issue: No]
  Four task sessions will be done 24-72 hours apart

- Change in working memory, as measured by reaction time (RT) across n-back conditions on a modified version of the n-back task [Time Frame: Baseline and following each of the RTFF sessions, up to 2 weeks] [Designated as safety issue: No]
  Four task sessions will be done 24-72 hours apart

- Change in long-term memory formation, as measured by memory trials [Time Frame: Baseline and following each of the RTFF sessions, up to 2 weeks] [Designated as safety issue: No]
  Four task sessions will be done 24-72 hours apart

- Change in inhibitory control, as measured by the Conners' Continuous Performance Task (CPT) [Time Frame: Baseline and following each of the RTFF sessions, up to 2 weeks] [Designated as safety issue: No]
Four task sessions will be done 24-72 hours apart

- Change in attention, as measured by reaction time (RT) variability on the CPT [ Time Frame: Baseline and following each of the RTFF sessions, up to 2 weeks ] [ Designated as safety issue: No ]

Estimated Enrollment: 40
Study Start Date: April 2016
Estimated Primary Completion Date: April 2018 (Final data collection date for primary outcome measure)

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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>Experimental: Self activation of VTA bold signal Participants meeting study inclusion will then be scheduled for 4 fMRI sessions to assess and manipulate the ability to self-stimulate VTA activation. Each session will contain the same tasks and instructions. The experimental imaging task sessions will be done 24-72 hours apart and will consist of two types of runs: Test Runs (one pre-test and post-test each) and three Training Runs. Participants will be instructed to achieve heightened state of motivation using personally relevant thoughts and imagery.</td>
<td>Other: Real-Time functional Magnetic Resonance Imaging Feedback (RTFF) During the Activate trials, the thermometer will display the weighted average of VTA BOLD activation, dynamically updated every second. This continuously updated thermometer is the primary feedback mechanism.</td>
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**Detailed Description:**

The study involves a screening visit and 4 experimental task sessions. During the screening visit subjects will undergo psychiatric screening to determine if they meet criteria for a diagnosis of ADHD. Participants who meet criteria for a diagnosis of ADHD will also have the following tests done at screening: breath alcohol test, urine drug screen and urine cotinine (by product of tobacco) screening and intelligence quotient (IQ) assessment. Eligible participants will complete a battery of cognitive assessments.

Participants meeting study inclusion will then be scheduled for 4 fMRI sessions to assess and manipulate the ability to self-stimulate VTA activation. Each session will contain the same tasks and instructions. The experimental imaging task sessions will be done 24-72 hours apart and will consist of two types of runs: Test Runs (one pre-test and post-test each) and three Training Runs.

The purpose of the Pre-Test is to establish a baseline level of self-generated VTA activation prior to receiving RTFF.

The Post-Test is designed to assess whether participants are better able to self-induce VTA BOLD signal in the absence of feedback (after receiving RTFF).

Participants will begin and end each scanning session with a 2-minute resting state scan. Participants will rest and fixate at a cross hair.
The purpose of the first run is to acquire data in functional space to facilitate registration of the VTA probabilistic atlas (MNI space) to functional space.

The Pre-Test and Post-Test runs will be identical and will have two trial types: Activate and Count.

During the Activate trials participants will be instructed to try to increase activity (BOLD signal) within their VTA. Specifically, we will instruct participants to try to get themselves into a heightened state of motivation using personally relevant thoughts and imagery. Importantly, they will be encouraged to optimize strategies for themselves.

During the Count trials, participants will be instructed to count backwards. The purpose of these trials is to standardize the baseline period and to provide a distractor task to prevent engagement in activation strategies. There will be 5 repetitions of both trial types, separated by a jittered inter-trial-interval (ITI; total duration 4 minutes, 5 seconds).

The purpose of the subsequent training runs (n=3/day on each of the 4 days) is to provide participants with RTFF to assist them in increasing their VTA BOLD signal.

The training runs will consist of three trial types: Activate, Count, and Rest. For both Activate and Count Trials, participants will be given the same instructions as during the test runs. During the Rest trials participants will be instructed to rest and not think of anything in particular. The Activate and Rest trials will include a thermometer display, as described below. Each trial type will be repeated 5 times per run, separated by a jittered ITI (total duration 6 minutes, 18 seconds).

Following the Post-Test each day, the Cognitive Battery assessments will be repeated with the subject out of the scanner.

Eligibility

Ages Eligible for Study: 18 Years to 45 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- 18-45 years of age
- Male or Female
- Confirmed diagnosis, any subtype as determined by the clinician administered Conner's Adult ADHD Diagnostic Interview for DSM-IV (CAADID) and clinical interview using the Mini International Neuropsychiatric Interview (MINI)
- T-Score > 65 on one of the DSM-IV relevant scales (Inattentive Symptoms, Hyperactive-Impulsive Symptoms, Total Symptoms or ADHD Index) on both the Self-Report and Observer versions of the Conner’s Adult ADHD Rating Scales (CAARS)
- Cognitive functioning > 80 as assessed by the Kaufman Brief Intelligence test, Second Edition (KBIT-II)

Exclusion Criteria:

- History of chronic/significant medical condition
- Current or past 6 month use of prescription medications for ADHD or other psychiatric condition
- Meets criteria for any other Axis I Disorder (determined the Mini International Neuropsychiatric Interview (MINI) other than nicotine dependence that is significantly impairing and would contraindicate participation in the present study
- Meets criteria for any Axis II Disorder
- Current substance abuse or dependence or history within the last 12 months; expired breath alcohol level > 0.0; Positive urine drug screen for any of the following: cannabis, amphetamines, opioids, benzodiazepines, barbiturates, cocaine
- Inability to understand written and/or spoken English language
- Claustrophobia or other contraindications to MRI scanning
- If female, pregnancy as determined by urine pregnancy test on each day of MRI scanning
- Presence of any metal in the body (e.g., implant, non-removable piercing, IUD)
- Head injury resulting in loss of consciousness
- Worked with metal (e.g., welding) or had an injury to the eye involving metal
- Weigh more than 250 pounds

Contacts and Locations
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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02723708

Contacts
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Sponsors and Collaborators
Duke University
National Institute of Mental Health (NIMH)

Investigators
Principal Investigator: Scott Kollins, PhD Duke University

More Information
No publications provided

Responsible Party: Duke University
ClinicalTrials.gov Identifier: NCT02723708 History of Changes
Other Study ID Numbers: Pro00070749 1R01MH106751
Study First Received: March 24, 2016
Last Updated: March 29, 2016
Health Authority: United States: Institutional Review Board
Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity
Attention Deficit and Disruptive Behavior Disorders
Mental Disorders
Mental Disorders Diagnosed in Childhood

ClinicalTrials.gov processed this record on March 29, 2016