

Study of Cognition and Control in Youths

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ClinicalTrials.gov

Identifier:

NCT03393390

Recruitment Status :

Recruiting

First Posted : January
8, 2018

Last Update Posted :
January 8, 2018

See **Contacts and
Locations**

Sponsor:

University of Michigan

Information provided by (Responsible Party):

Chandra Sekhar Stripada, University of Michigan

- **Study Details**
- **Tabular View**
- **No Results Posted**

- Disclaimer
- How to Read a Study Record

Study Description

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Brief Summary:

The purpose of this study is to learn more about the functioning of particular types of regions of the brain, specifically, those related to externalizing disorders such as Attention Deficit Hyperactivity Disorder (ADHD), Oppositional Defiance Disorder (ODD), and Conduct Disorder (CD). Brain function of children and adolescents with externalizing disorders such as ADHD, ODD, and CD will be compared to the brain function of those without. Functional Magnetic Resonance Imaging (fMRI) will be used to monitor brain activity at work and at resting states.

Condition or disease	Intervention/treatment
Attention Deficit Hyperactivity Disorder Oppositional Defiant Disorder Conduct Disorder	Diagnostic Test: Clinical Assessment Visit Other: fMRI scan

Detailed Description:

The goal of this research proposes to take a developmental neuroimaging approach to elucidating brain mechanisms that lead to distinct forms of impulsivity in youth with externalizing disorders, including attention-deficit/hyperactivity disorder (ADHD), oppositional defiant disorder (ODD), and conduct disorder (CD). Roughly 12-15% of youth suffer from at least one of these disorders (many of them have more than one) and they go on to experience serious adverse outcomes over the course of their lifetimes including increased rates of substance abuse, violence and criminality, maladjustment, and suicide. The absence of a biological, and in particular a neurodevelopmental, understanding of the pathophysiology of distinct kinds of impulsivity has been a major barrier to improving clinical care for impulsive youth; it has hindered efforts at building better nosology, earlier and more reliable diagnosis, and more effective treatments.

The NIMH Research Domain Criteria (RDoC) Initiative encourages clinical scientists to no longer think in terms of single categorical diagnoses (whose boundaries may in fact be drawn incorrectly), but rather to identify disorder-

spanning constructs. Inspired by the RDoC Initiative, our research aims to delineate the neural mechanisms of distinct forms of impulsivity in youth from a transdiagnostic perspective that spans the three main externalizing disorders, ADHD, CD, and ODD, as well as across subtypes of these disorders (e.g., ADHD inattentive, hyperactive/impulsive, and combined types). More specifically, the study aims to develop a new class of imaging-based biomarkers for specific forms of impulsivity—markers that are rooted in aberrant brain maturation patterns.

Developing neuroimaging markers of impulsivity could have a number of important clinical impacts. For example, these markers could provide a basis for more objective diagnosis, facilitate earlier diagnosis, catalyze the development of new treatments, and help to guide the selection of treatments.

For this study, 270 youth subjects will be recruited, 135 with at least one externalizing disorder and 135 matched controls, between the ages of 6-18. All participants will receive the following: 1) a comprehensive clinical/neurological assessment to quantify impulsivity symptoms; and 2) an fMRI session (structural, diffusion tensor imaging, resting, and task). Three cohorts are recruited: childhood (6-9 years; n=90), early adolescence (10-13 years; n=90), and middle adolescence (14-18; n=90).

The main aim of the study is to use imaging results to generate normative maturational curves for each component in the brain's regulatory control architecture using a multi-level linear mixed effects model. Multivariate models that predict types of impulsivity based on component expression will then be constructed.

Study Design

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Study Type : Observational

Estimated Enrollment : 270 participants

Observational Model: Case-Control

Time Perspective: Prospective

Official Title: Study of Cognition and Control in Youths

Actual Study Start Date : March 17, 2016

Estimated Primary Completion Date : March 2021

Estimated Study Completion Date : March 2022

Groups and Cohorts

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Group/Cohort	Intervention/treatment
<p>Healthy Controls</p> <p>Subjects in this group will be defined as healthy controls after meeting with a clinician and determining that they do not meet the diagnostic criteria for any externalizing disorders or other psychiatric disorders.</p>	<p>Diagnostic Test: Clinical Assessment Visit</p> <p>Subjects will meet with a clinician who will determine if they meet diagnostic criteria for an externalizing disorder.</p> <p>Other: fMRI scan</p> <p>Subjects will undergo an fMRI scan where images will be taken for observational purposes only, not as a means of diagnosis.</p>
<p>Externalizing</p> <p>Subjects in this group will be defined as externalizing if the clinician determines that they meet the diagnostic criteria for one or more externalizing disorders, such as ADHD, ODD, or CD.</p>	<p>Diagnostic Test: Clinical Assessment Visit</p> <p>Subjects will meet with a clinician who will determine if they meet diagnostic criteria for an externalizing disorder.</p> <p>Other: fMRI scan</p> <p>Subjects will undergo an fMRI scan where images will be taken for observational purposes only, not as a means of diagnosis.</p>

Outcome Measures

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Primary Outcome Measures :

1. Maturation Curves for regulatory control structures in brain [Time Frame: 5 years]
Resting state fMRI functional connectivity maps will be used to generate normative growth curves for each component in the brain's regulatory control architecture using a multi-level linear mixed effects model. Each individual's deviation from their expected growth (based on the normative growth chart) is calculated and is utilized to predict clinical outcome variables.

Eligibility Criteria

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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:	6 Years to 18 Years (Child, Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

Community sample, clinic patients.

Criteria

Inclusion Criteria:

- The healthy control group will be made up of approximately 135 subjects between the ages of 6-18 at the start of the study who meet no diagnostic criteria for any externalizing disorders.
- The externalizing group will be made up of approximately 135 subjects between the ages of 6-18 at the start of the study who meet the diagnostic criteria for at least one externalizing disorder (ADHD, ODD, CD, etc)

Exclusion Criteria:

- IQ below 80
- History of significant head injury (e.g. loss of consciousness greater than 5 minutes, report of skull fracture or cerebral hemorrhage, or hospitalization)
- Presence of any significant medical or neurological condition that might impact activity in the neural circuits of interest or that might increase risk of participation for the subject (e.g. seizure disorder or mass lesions)
- Contraindications to MRI (e.g. metal objects in body, claustrophobia)
- Abnormal vision after correction

Contacts and Locations

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*Please refer to this study by its [ClinicalTrials.gov](#) identifier (NCT number): **NCT03393390***

Contacts

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Principal Investigator: Chandra Sripada, PhD

Recruiting

Sponsors and Collaborators

University of Michigan

Investigators

Principal Investigator: Chandra Sripada, PhD University of Michigan

More Information

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Responsible Party: Chandra Sekhar Sripada, Associate Professor of Psychiatry and Philosophy, University of Michigan

ClinicalTrials.gov Identifier: NCT03393390 History of Changes

Other Study ID Numbers: HUM00088188

First Posted: January 8, 2018 Key Record Dates

Last Update Posted: January 8, 2018

Last Verified: January 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Undecided

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

Studies a U.S. FDA-regulated Device Product: No

Additional relevant MeSH terms:

Disease

Attention Deficit Disorder with Hyperactivity

Conduct Disorder

Attention Deficit and Disruptive Behavior Disorders

Pathologic Processes

Neurodevelopmental Disorders

Mental Disorders