System for Determining Ideal Drug Doses for ADHD - Stages 1 and 2

ClinicalTrials.gov Identifier: NCT03523663

Recruitment Status : Recruiting
First Posted : May 14, 2018
Last Update Posted : May 14, 2018
See **Contacts and Locations**

Sponsor:
University of Wisconsin, Madison
Information provided by (Responsible Party):
University of Wisconsin, Madison

Study Description

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Brief Summary:

The goal of this study is to create a formal, quantitative methodology to determine what is the most beneficial dose of Central Nervous System (CNS) stimulant (Ritalin, methylphenidate) to improve cognitive and behavioral function of children diagnosed with Attention Deficit Hyperactivity Disorder (ADHD) individually. If successful, it will change the way in which the dose of CNS stimulant for treating ADHD is determined for children in need of therapeutic intervention. The project will be focused on developing the necessary methodology to analyze the children's data with the drift-decision model (DDM), and to develop the required technology, i.e., a computer game with which to measure cognitive/behavioral function and its validation with eye-tracking measurements.

Condition or disease	Intervention/treatr
Attention Deficit Hyperactivity Disorder	Other: no intervention. measure eye movement da

Study Design

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Study Type :	Observational
Estimated Enrollment :	45 participants
Observational Model:	Cohort
Time Perspective:	Cross-Sectional
Official Title:	Algorithm to Quantitatively Determine the Ideal Drug Dose to Treat Attention Deficit Hyperactivity Disorder

Study Start Date :	January 2016
Estimated Primary Completion Date :	June 2019
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

Groups and Cohorts
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Group/Cohort	Intervention/treatment
Control healthy children without ADHD or other mental health issues	Other: no intervention. measure eye movement data
ADHD children diagnosed with ADHD	Other: no intervention. measure eye movement data

Outcome Measures
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Primary Outcome Measures :

1. Task choice [Time Frame: At the time of testing (the investigators are measuring acute effects, not following outcomes based on a treatment)]

   Subjects will perform different cognitive tasks and we will record their choices.

2. Reaction time [Time Frame: At the time of testing (the investigators are measuring acute effects, not following outcomes based on a treatment)]

   The investigators record how long it took them to make their choices.

3. Eye position [Time Frame: At the time of testing (the investigators are measuring acute effects, not following outcomes based on a treatment)]

   The tasks are eye movement based. The investigators record where the subjects were looking and when.

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:	8 Years to 12 Years (Child)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

children

Criteria

Inclusion Criteria:

- 8-12 years of age;
- Accompanied by caregiver (parent or legal guardian);
- Able to understand and speak English;
- Able to read basic English;
- No counseling or current/past history of psychiatric illness, as confirmed by the Child Behavior Checklist (CBCL) and Conner's rating scale

Exclusion Criteria:

- a. Active psychosis or suicidality; b. History of primary psychotic disorder (e.g., schizophrenia) or bipolar disorder; c. Recent (past 2 weeks) substance abuse or dependence; d. History of brain damage or significant developmental delay; e. Unstable medical condition such as newly diagnosed Type I Diabetes or Rheumatoid arthritis; f. Use of oral steroids; g. Participation in the last 30 days in a clinical study involving an investigational drug; h. Current use of a psychotropic medicine

Contacts and Locations

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03523663***

Contacts

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Contact: Luis C Populin, PhD 608-265-6711 lpopulin@wisc.edu

Locations

United States, Wisconsin

Wisconsin Institutes of Medical Research **Recruiting**
Madison, Wisconsin, United States, 53705
Contact: Abigail Z Rajala, PhD 608-265-6711 arajala@wisc.edu
Contact: Luis Populin, PhD 608-265-6451 lpopulin@wisc.edu

Sponsors and Collaborators

University of Wisconsin, Madison

Investigators

Principal Investigator: Luis C Populin, PhD University of Wisconsin, Madison

More Information

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ClinicalTrials.gov Identifier:	NCT03523663 History of Changes
Other Study ID Numbers:	2015-0857
First Posted:	May 14, 2018 Key Record Dates
Last Update Posted:	May 14, 2018
Last Verified:	May 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity
Hyperkinesis
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders
Dyskinesias
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms