

# Stimulant Effects on Disruptive Behavior

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ClinicalTrials.gov Identifier: NCT03420339

Recruitment Status : Not yet recruiting

First Posted : February 2, 2018

Last Update Posted : February 2, 2018

See **Contacts and Locations**

## Sponsor:

Matthew O'Brien

## Information provided by (Responsible Party):

Matthew O'Brien, University of Iowa

## • Study Details

- **Tabular View**
- **No Results Posted**

- Disclaimer
- How to Read a Study Record

## Study Description

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Brief Summary:

The goal of this study is to determine the effects of stimulant medication on disruptive behavior, function, preference and choice; however, it is primarily methodological and will add to current research by establishing an effective evaluation of the impact of stimulant medication on these behaviors. Three behavior assessments for children and adolescents diagnosed with AD/HD who exhibit disruptive behavior will be conducted:

1. Preference assessments will be conducted to determine whether preference for social and nonsocial items and activities differs under medication and non-medication conditions.
2. Functional analyses will be conducted to determine whether stimulant medication has an effect on the frequency and function or purpose of disruptive behavior.
3. Choice assessments will be conducted to evaluate the impact of stimulant medication on impulse control/delay discounting.

This study will be conducted in three phases. For each of the 5 to 10 participants there will be 8 total visits. The first 4 visits will entail a preference assessment, followed by a functional analysis. On visits 1 and 3, the participant will be asked to take his/her stimulant medication as is typically done; however, on visits 2 and 4, the participant will be asked to refrain from taking the medication.

For visits 5-8, participants will continue to participate in preference assessments, but will also be presented with a choice arrangement with work and play. In the choice arrangement, participants will be given four work cards and four play cards that they can organize in any order. Work cards will be associated with a brief academic task and play cards will be associated with a brief play period using high-preferred toys/activities. On visits 5 and 7 the participant will be asked to take his or her stimulant medication as usual, while on visits 6 and 8 the participant will be asked to refrain from taking his or her medication.

Condition or disease	Int
Attention Deficit Hyperactivity DisorderProblem Behavior	Drug: Stimula

## Show Detailed Description

### Study Design

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Study Type : Observational

Estimated Enrollment : 10 participants

Observational Model: Case-Only

Time Perspective: Prospective

Official Title: The Effects of Stimulant Medication on Disruptive Behavior, Choice, and Preference in Children and Adolescents Exhibiting Disruptive Behavior

Anticipated Study Start Date : February 2018

Estimated Primary Completion Date : January 2019

Estimated Study Completion Date : January 2019

### Groups and Cohorts

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Group/Cohort	Intervention/treatment
Subjects on stimulant medication All participants: Children and adolescents diagnosed with AD/HD, displaying disruptive behavior, and taking stimulant medication.	Drug: Stimulant The stimulants used must meet FDA dosage guidelines for age. Other Names: <ul style="list-style-type: none"><li>• Adderall</li><li>• Concerta</li><li>• Aptensio</li><li>• Daytrana</li><li>• Metadate</li><li>• Quillivant</li><li>• Ritalin</li><li>• Focalin</li><li>• Vyvanse</li></ul>

### Outcome Measures

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Primary Outcome Measures :

1. Change in Behavioral Function [ Time Frame: Weekly (at each visit): week 1, week 2, week 3, week 4; Change in behavioral function will be compared using data from weeks one and three (on medication) versus weeks two and four (off medication). ]

Data will be collected and graphed on the frequency (rate per minute) of problem behavior. Visual inspection of graphs will determine differentiation across the four conditions (three test conditions and the freeplay/control condition) to identify the function(s) of the target behavior. Changes in behavioral function will be determined by comparing data week to week for the first four weeks. Behavioral function while on medication, which will occur at week one and week three will be compared to

behavioral function at week two and week four. Differences between weeks one and three and weeks two and four will be considered as change in behavioral function.

2. Change in Item Preference [ Time Frame: Weekly (at each visit): week 1, week 2, week 3, week 4, week 5, week 6, week 7, week 8; we will compare data from weeks 1, 3, 5, and 7 (on medication) versus weeks 2, 4, 6, and 8 (off medication) ]

Data on change in item preference will be collected week to week for all eight weeks. We will determine preference for an item/activity based upon the duration of time engaged with an item in the therapy room during the free operant preference assessment. Data will be compared week to week, with a focus on changes from weeks one, three, five, and seven (on medication) to weeks two, four, six, and eight (off medication). Differences in item engagement will indicate difference in item preference.

3. Change in Preference for Social and Non-Social Activities [ Time Frame: Weekly (at each visit): week 1, week 2, week 3, week 4, week 5, week 6, week 7, week 8; Changes in preference will be determined weekly, with a focus on differences between time points on medication and weeks off of medication. ]

Data will be collected on the percentage of trials an activity is selected and whether it was selected with attention or without attention for each item/activity in the therapy room of the multiple stimulus without replacement assessment. Preference for social versus non-social activities will be determined by the participant's selection during the multiple stimulus without replacement assessment. The change in preference for activities with attention and activities without attention will be determined by comparing data weekly, with a focus on differences between data in weeks 1, 3, 5, and 7 (on medication) versus weeks 2, 4, 6, and 8 (off medication).

4. Changes in Impulsivity in Choice-Making [ Time Frame: Weekly (at each visit): week 5, week 6, week 7, week 8 ]

Data will be collected on the sequence chosen by the subject and scored based upon the degree to which work sessions were placed up front and play activities were placed at the end. Choices whereby play activities are front loaded (i.e., more play activities earlier in the schedule) will be scored as more impulsive on a point system and choices whereby work activities are front loaded (i.e., more work activities earlier in the schedule) will be scored as less impulsive. Differences in impulsivity will be determined on a week to week basis, with a focus on differences between weeks on medication (weeks 5 and 7) and weeks off of medication (weeks 6 and 8).

#### Secondary Outcome Measures :

1. Rate of Problem Behavior [ Time Frame: Weekly (at each visit): week 1, week 2, week 3, week 4, week 5, week 6, week 7, week 8 ]

Data will be collected in all assessment sessions on the rate of problem behavior and compared for sessions on medication and sessions off medication.

2. Item Engagement [ Time Frame: Weekly (at each visit): week 1, week 2, week 3, week 4, week 5, week 6, week 7, week 8 ]

Data will be collected in all assessment sessions involving play with items/activities on item engagement and compared for sessions on medication and sessions off medication.

3. Compliance [ Time Frame: Weekly (at each visit): week 1, week 2, week 3, week 4, week 5, week 6, week 7, week 8 ]

Data will be collected on compliance to demands for all sessions involving work. Data will be compared for sessions on medication and sessions off medication.

## 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: 48 Months to 153 Months (Child)  
Sexes Eligible for Study: All  
Sampling Method: Non-Probability Sample

### Study Population

Subjects for this study will be referred from one of several tertiary care clinics that specialize in (a) the diagnosis and medical treatment for AD/HD, or (b) the assessment and treatment of severe and challenging behavior.

### Criteria

Inclusion Criteria:

1. Participant must be a child or adolescent between the ages of 4 years, 0 months, and 13 years, 0 months (participants must not be older than 12 years, 11 months).
2. Participant must have a valid diagnosis of attention deficit/hyperactivity disorder (AD/HD). No specification of type (e.g., predominately inattentive type, predominately hyperactive-impulsive type, or combined type) will be necessary.
3. Participant must exhibit disruptive behavior, defined as one or more of the following:
  1. physical or verbal aggression towards others: Hitting, kicking, biting, scratching, choking, spitting at, or throwing items at another person, and/or making insults, threats, or swearing at another person.
  2. self-injury: Hitting self, biting self, banging head on an object/hard surface, pinching self, or scratching self with visual skin damage.
  3. destruction: Damaging (or attempts to damage) personal or public property (e.g., breaking an object into two or more pieces, using an object to break other objects, ripping objects or parts of objects from walls, floors, or furniture, and denting cars, objects, or walls.)
  4. noncompliance: Regular occurrence of verbal refusal (e.g., saying "no", "I don't want to", "I won't do it" or "not now") to any academic or non-academic request, and/or any response that does not match the delivered instruction within 30 seconds from the time the instruction was delivered.
  5. tantrum: Crying (i.e., any vocalizations [sounds or words] accompanied by facial contraction with and without tears for any period of time) and/or screaming (occurrence of vocalizations above normal conversational volume for any period of time), with or without body flailing.

6. an active diagnosis of disruptive behavior disorder or oppositional defiant disorder.
4. Participant must already be prescribed a stimulant medication for the treatment of AD/HD symptoms and at an approved dose for age.

Exclusion Criteria:

1. a diagnosis of autism, conduct disorder, or intellectual disability in the moderate, severe or profound range.
2. prescribed or taking a stimulant dosage outside of recommended therapeutic range.

## Contacts and Locations

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### 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): **NCT03420339***

## Contacts

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## Sponsors and Collaborators

Matthew O'Brien

### Investigators

Principal Investigator: Matthew J O'Brien, PhD University of Iowa

### More Information

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Responsible Party: Matthew O'Brien, Clinical Assistant Professor, University of Iowa

ClinicalTrials.gov Identifier: NCT03420339 History of Changes

Other Study ID Numbers: 201709737

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Last Verified: February 2018

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

Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: Yes

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

Product Manufactured in and Exported from the U.S.: No

Keywords provided by Matthew O'Brien, University of Iowa:

stimulant medication

behavioral function

preferences

delay discounting

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity  
Problem Behavior  
Attention Deficit and Disruptive Behavior Disorders  
Neurodevelopmental Disorders

Mental Disorders  
Behavioral Symptoms  
Central Nervous System Stimulants  
Physiological Effects of Drugs