Efficacy of Lisdexamfetamine Dimesylate for Promoting Occupational Success in Young Adults with 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: NCT03446885

Recruitment Status: Not yet recruiting
First Posted: February 27, 2018
Last Update Posted: February 27, 2018

Sponsor:
Gregory Fabiano

Information provided by (Responsible Party):
Gregory Fabiano, State University of New York at Buffalo

Brief Summary:
There has been little research on the third area of impairment noted in the Diagnostic and Statistical Manual of Mental Disorders - "occupational functioning." Individuals with ADHD experience job-related impairments including a greater likelihood of being unemployed and not enrolled in school and for those that were employed they were in a lower status occupation, relative to typically-developing comparison peers. The current literature on analogue workplace settings and the effects of lisdexamfetamine dimesylate includes office-based tasks similar to school seat work. Unfortunately, this is inconsistent with the typical work environment most common for individuals with disabilities such as ADHD where food preparation is the most common job following high school. Therefore, medication effects in this type of setting, most common for individuals with ADHD entering the workforce, need to be studied. The investigators propose to study workplace behavior in an analogue work setting in a laboratory "pizza place." Individuals with ADHD will participate in an interview with a supervisor each day, have a list of deliveries that need to be managed, deal with situations that require occupational judgment and appropriate customer service, and drive to make deliveries accurately and on-time. These behaviors can be reliably assessed within the laboratory. Twenty young adults will participate in two "workdays" within a randomized, double-blind, placebo-controlled design wherein participants will be administered placebo and .3 mg/kg lisdexamfetamine dimesylate in a counter-balanced order.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Drug: Lisdexamfetamine Dimesylate</th>
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<tbody>
<tr>
<td>Attention Deficit Disorder With Hyperactivity</td>
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Study Design

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Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 20 participants
Allocation: Randomized

Intervention Model: Crossover Assignment

Masking: Triple (Participant, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: Efficacy of Lisdexamfetamine Dimesylate for Promoting Occupational Success in Young Adults With Attention-deficit/Hyperactivity Disorder

Anticipated Study Start Date: April 1, 2018

Estimated Primary Completion Date: December 31, 2018

Estimated Study Completion Date: December 31, 2018

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
Drug Information available for: Lisdexamfetamine Lisdexamfetamine dimesylate
U.S. FDA Resources

Arms and Interventions

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Intervention Details:
Drug: Lisdexamfetamine Dimesylate 40 MG
Lisdexamfetamine Dimesylate 40 MG administered orally
Drug: Placebo
Placebo capsule administered orally

Outcome Measures

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Primary Outcome Measures:

1. Ratings of Job Application Quality [Time Frame: Change between session 1 and 2 (each session is one day in duration)]

   Three independent coders will review each de-identified application. Following the review of the application, coders will complete a rating form that asks them to make an overall evaluation regarding whether the person was an acceptable job candidate for an interview using a scale of 1 ("definitely not") to 5 ("definitely"). Average rating across coders will be used as the dependent measure.

2. Ratings of Job Interview Performance [Time Frame: Change between session 1 and 2 (each session is one day in duration)]

   Three coders who are unaware of the study participant identities or group status will view the job interview videotape and completed a form. Raters will provide a rating of their overall impression of the interview behavior ranging from a score of one (Poor) to four (Outstanding). The average score of the coders will be utilized as a dependent measure.
3. Objective Observation of Workplace Productivity [ Time Frame: Change between session 1 and 2 (each session is one day in duration) ]

The dependent measures from this aspect of the study are the number of items completed correctly out of the total number of assigned items (i.e., 225).

4. Inattentive/Overactive Rating [ Time Frame: Change between session 1 and 2 (each session is one day in duration) ]

In addition to ratings of the interview performance, the rater also will complete the five-item inattentive/overactive (I/O) factor of the Iowa Conners rating scale (Atkins, Pelham, & Licht, 1989; Loney & Milich, 1982; Pelham, Milich, Murphy, & Murphy, 1989). The five items are rated on a scale of Not at all (0) to Very Much and the sum of these items represents the score. The dependent measure will be the score averaged across raters.

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: 16 Years to 25 Years (Child, Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:
- diagnosis of ADHD
- parental permission and/or teen consent/assent as appropriate
- between 16-25 years of age
- IQ greater than or equal to 70
- permit or license to drive
- ability to read and understand English

Exclusion Criteria:
- any medical condition that would contraindicate use of stimulant medication
- any prior adverse response to lisdexamfetamine dimesylate or other stimulant medication
- use of concurrent, non-stimulant psychoactive medication
- diagnosis of schizophrenia or presence of thought disorder symptoms
- autism spectrum disorder

Contacts and Locations
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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03446885

Locations

United States, New York

SUNY at Buffalo  
Not yet recruiting

Buffalo, New York, United States, 14214  
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Sponsors and Collaborators
Gregory Fabiano

More Information
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Responsible Party:  
Gregory Fabiano, Professor, State University of New York at Buffalo

ClinicalTrials.gov Identifier:  
NCT03446885  
History of Changes

Other Study ID Numbers:  
IIR-USA-001277

First Posted:  
February 27, 2018

Last Update Posted:  
February 27, 2018

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.:  
Yes

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity  
Lisdexamfetamine Dimesylate

Hyperkinesis  
Central Nervous System Stimulants

Attention Deficit and Disruptive Behavior Disorders  
Physiological Effects of Drugs

Neurodevelopmental Disorders  
Dopamine Uptake Inhibitors

Mental Disorders  
Neurotransmitter Uptake Inhibitors

Dyskinesias  
Membrane Transport Modulators

Neurologic Manifestations  
Molecular Mechanisms of Pharmacological Action

Nervous System Diseases  
Dopamine Agents

Signs and Symptoms  
Neurotransmitter Agents