LearningRx Cognitive Training for ADHD

This study is enrolling participants by invitation only.

Sponsor:
Gibson Institute of Cognitive Research

Information provided by (Responsible Party):
Gibson Institute of Cognitive Research

ClinicalTrials.gov Identifier:
NCT02917109

First received: September 26, 2016
Last updated: NA
Last verified: September 2016
History: No changes posted

Purpose

The purpose of this investigation is to conduct a series of case studies on the impact of LearningRx cognitive training on cognitive skills, brain structure, and daily functioning for participants with ADHD.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder (ADHD)</td>
<td>Behavioral: LearningRx cognitive training</td>
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</table>

Study Type: Interventional

Study Design: Endpoint Classification: Efficacy Study
             Intervention Model: Single Group Assignment
             Masking: Open Label
             Primary Purpose: Treatment

Official Title: LearningRx Cognitive Training for ADHD: A Multiple Baseline Study Across Cases

Further study details as provided by Gibson Institute of Cognitive Research:

Primary Outcome Measures:

- Evidence of overall cognitive function improvement [ Time Frame: within 14 days after completing the intervention ] [ Designated as safety issue: No ]
  Confirmed by change in pretest to post-test scores on the Woodcock Johnson IV - Tests of Cognitive Abilities
Secondary Outcome Measures:

- Evidence of change in brain activity [Time Frame: within 30 days after completing the intervention]  
  [Designated as safety issue: No]  
  As confirmed by pretest to post-test changes in electrical activity measured by qEEG

- Evidence of reduction in ADHD symptoms [Time Frame: within 14 days after completing the intervention]  
  [Designated as safety issue: No]  
  As confirmed by pretest to post-test changes on the ADHD Rating Scale

- Evidence of change in brain structure [Time Frame: within 30 days after completing the intervention]  
  [Designated as safety issue: No]  
  Confirmed by change in pretest to post-test neuroimaging using MRI

- Evidence of improvement in visual or auditory attention [Time Frame: with 14 days after completing the intervention]  
  [Designated as safety issue: No]  
  Confirmed by change in pretest to post-test scores on the Conners Continous Performance Test (CPT-3) and Auditory Attention Test (CATA)

Estimated Enrollment: 3

Study Start Date: September 2016

Estimated Study Completion Date: August 2017

Estimated Primary Completion Date: April 2017 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</table>
| Experimental: LearningRx cognitive training | Behavioral: LearningRx cognitive training  
  A clinician will deliver three 90-minute cognitive training sessions per week for 14 weeks. There are 16 different categories of leveled training procedures sequenced in intensity and difficulty for a total of 530 training tasks. |

Detailed Description:
Using a multiple baseline design across cases with start point randomization, the proposed study will examine the outcomes from LearningRx one-on-one cognitive training across domains on standardized measures used to monitor treatment effectiveness for ADHD.

Eligibility

Ages Eligible for Study: 15 Years to 22 Years (Child, Adult)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:
- Age 15-22 previously diagnosed with ADHD
- High school students or college students with a prior diagnosis of ADHD living in the greater Colorado Springs area

Exclusion Criteria:
- No braces, metal implants, or claustrophobia that would contraindicate magnetic resonance imaging

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: NCT02917109

Locations

United States, Colorado

Gibson Institute of Cognitive Research
Colorado Springs, Colorado, United States, 80919

Sponsors and Collaborators
Gibson Institute of Cognitive Research

Investigators

Principal Investigator: Christina Ledbetter, PhD    Gibson Institute of Cognitive Research
Study Director: Amy L. Moore, PhD    Gibson Institute of Cognitive Research

More Information

Responsible Party: Gibson Institute of Cognitive Research
ClinicalTrials.gov Identifier: NCT02917109    History of Changes
Other Study ID Numbers: GICR-0916-A
Study First Received: September 26, 2016
Last Updated: September 26, 2016
Health Authority: United States: Institutional Review Board

Individual Participant Data

Plan to Share IPD: Yes
Plan Description: Will add to Harvard Dataverse

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders

ClinicalTrials.gov processed this record on September 28, 2016