Software Treatment for Actively Reducing Severity of ADHD - Follow Up (STARS-ADHD2)

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified July 2016 by Akili Interactive Labs, Inc.

Sponsor:
Akili Interactive Labs, Inc.

Information provided by (Responsible Party):
Akili Interactive Labs, Inc.

ClinicalTrials.gov Identifier:
NCT02828644

First received: June 30, 2016
Last updated: July 7, 2016
Last verified: July 2016
History of Changes

Purpose
This is an exploratory study to assess potential maintenance of clinical benefit (cognition and symptoms) following 4 weeks of at-home digital therapy in ADHD children.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Disorder With Hyperactivity</td>
<td>Device: EVO</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: An Exploratory Study to Assess the Sustained Effects of Digital Therapy in Pediatric Subjects 8 to 12 Years Old With Attention Deficit Hyperactivity Disorder (ADHD)

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
Further study details as provided by Akili Interactive Labs, Inc.:

Primary Outcome Measures:
- Assess sustained effects in attention from end-of-treatment (Follow-Up Day 0) to Follow-Up Day 28 within groups that were previously randomized to receive 4 weeks of digital therapy [Time Frame: Day 28]
  [Designated as safety issue: No]
  TOVA 8 API (Attention Performance Index)

Secondary Outcome Measures:
- Assess sustained effects in attention from end-of-treatment (Follow-Up Day 0) to Follow-Up Day 28 across groups that were previously randomized to receive 4 weeks of digital therapy [Time Frame: Day 28]
  [Designated as safety issue: No]
  TOVA 8 API (Attention Performance Index)

Estimated Enrollment: 330

Study Start Date: August 2016

Estimated Study Completion Date: June 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>
</tr>
</thead>
<tbody>
<tr>
<td>Active Comparator: EVO Multitasking</td>
<td>Device: EVO videogame-like digital therapy</td>
</tr>
<tr>
<td>EVO Multitasking is a digital intervention that requires subjects to navigate a character through a game-like space, while collecting objects, in a fixed period of time. The intervention was administered to the subjects during the parent study (Akili-001R)</td>
<td></td>
</tr>
<tr>
<td>Active Comparator: EVO Words</td>
<td>Device: EVO videogame-like digital therapy</td>
</tr>
<tr>
<td>EVO Words is a digital intervention that requires subjects to spell as many words as possible, by connecting letters in a game-like grid, in a fixed period of time. The intervention was administered to the subjects during the parent study (Akili-001R)</td>
<td></td>
</tr>
</tbody>
</table>

Detailed Description:
The study will be a blinded (investigators and outcome assessors), randomized (from parent study Akili-001R), parallel group, follow-up study of the sustained effects of 4-weeks of treatment with either EVO Multitasking game-based digital therapy or EVO Words game-based digital therapy.
The trial will consist of 4 visits: Screening (to be conducted at the same time as the end-of-study visit for the parent study Akili-001R), FU-Day 28 visit (conducted in clinic), and FU-Day 56 and FU-Day 84 visits (conducted remotely via electronically captured parent reported outcomes).

Eligibility

Ages Eligible for Study: 8 Years to 12 Years (Child)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Completed Akili Study Akili-001R including all clinical assessments at DAY28 per the study protocol
- Ability to comply with all the testing and requirements per this protocol

Exclusion Criteria:
- Participant is currently considered a suicide risk in the opinion of the Investigator, has previously made a suicide attempt, or has a prior history of, or is currently demonstrating active suicidal ideation or self-injurious behavior as measured by C-SSRS at screening
- Participant has demonstrated clinically significant deterioration in functioning as assessed by PI and other study staff that would contraindicate continued participation in the follow-up study

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: NCT02828644

Contacts

Contact: Iris Hindle, BA 919-668-4698 iris.hindle@duke.edu

Locations

United States, California
Avida, Inc.  Not yet recruiting
Newport Beach, California, United States, 92660
Contact: Audrey Kapelinski 949-336-6161 audrey@avidainc.com
Principal Investigator: Sharon Wigal, MD

United States, Florida
Florida Clinical Research Center, LLC  Not yet recruiting
Bradenton, Florida, United States, 32401
Contact: Andrew J Cutler, MD 941-747-7900 acutler@flcrc.com
Principal Investigator: Andrew J Cutler, MD
Florida Clinical Research Center, LLC
Brandenton, Florida, United States, 34208
Florida Clinical Research Center
Maitland, Florida, United States, 32751

United States, Missouri
Midwest Research Group  Not yet recruiting
  St. Charles, Missouri, United States, 63304
  Contact: Michael Varisella  636-946-8032  mvarisella@midwestresearchgroup.com
  Principal Investigator: Greg Mattingly, MD

United States, Nevada
Center for Psychiatry and Behavioral Medicine  Not yet recruiting
  Las Vegas, Nevada, United States, 89128
  Contact: Amanda Flansburg  702-838-0742  amanda.flans@gmail.com
  Principal Investigator: Ann Childress, MD

United States, North Carolina
Duke Child and Family Study Center  Not yet recruiting
  Durham, North Carolina, United States, 27705
  Contact: Leah Atkins  919-681-0013  leah.lakins@dm.duke.edu
  Principal Investigator: Naomi Davis
  Duke University
  Durham, North Carolina, United States, 27710

United States, Ohio
Cincinnati Children's Hospital Medical Center  Not yet recruiting
  Cincinnati, Ohio, United States, 45229
  Contact: Alina Tilford  513-803-1345  alina.tilford@cchmc.org
  Principal Investigator: Jeff Epstein, Ph.D.

Sponsors and Collaborators
Akili Interactive Labs, Inc.

Investigators
Principal Investigator: Scott Kollins, PhD  Duke Clinical Research Institution

More Information

Responsible Party: Akili Interactive Labs, Inc.
ClinicalTrials.gov Identifier: NCT02828644  History of Changes
Other Study ID Numbers: Akili-001R-FollowUp
Study First Received: June 30, 2016
Last Updated: July 7, 2016
Health Authority: United States: Institutional Review Board
Individual Participant Data
Plan to Share IPD: Undecided
Keywords provided by Akili Interactive Labs, Inc.:
ADHD

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

ClinicalTrials.gov processed this record on July 10, 2016