Software Treatment for Actively Reducing Severity of ADHD as Adjunctive Treatment to Stimulant

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: NCT03649074

Recruitment Status: Not yet recruiting
First Posted: August 28, 2018
Last Update Posted: August 28, 2018
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Sponsor:
Akili Interactive Labs, Inc.
Information provided by (Responsible Party):
Akili Interactive Labs, Inc.

Study Details

Tabular View
No Results Posted

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Study Description

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Brief Summary:
The purpose of this study is to determine the effects of combining AKL-T01 (with AKL-X01 symptom tracking) as adjunctive treatment to stimulant medication, and to understand the effects of AKL-T01 treatment (with AKL-X01 symptom tracking) in participants not recently on medication.

Condition or disease

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Device: AKL-T01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
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Detailed Description:
The study aims to enroll (203) participants, with a confirmed diagnoses of ADHD, at approximately 15 sites and will be divided between 2 cohorts; 130 participants will be enrolled in Cohort 1, and 73 participants will be enrolled in Cohort 2.

Cohort 1 will have been stable (adherence to a prescribed medication schedule) on a stimulant medication, but are inadequately managed by the stimulant (in the opinion of the investigator). The stimulant is managed by their own physician for at least 30 days before baseline. This is the "stimulant cohort."

Cohort 2 will have been stable without any stimulant medication for at least 30 days before the baseline. This is the "no stimulant" cohort.

For both cohorts, at least 7 and up to 30 days before baseline, participants' caretakers will begin using AKL-X01 (Fengo) to track their participants' symptoms and behaviors.

During Treatment Phase 1 (Days 1 through 28) participants in Cohort 1 (stimulant) will continue to receive their current stimulant plus the addition of AKL-T01. Participants in Cohort 2 (no stimulant) will just receive AKL-T01. For both cohorts, during this time the caretakers will monitor their child's symptoms daily with AKL-X01.

During the 1-Month Break (Days 29 through 56) between AKL-T01 treatment phases, participants in Cohort 1 (stimulant) will continue to receive their current stimulant. In both cohorts, AKL-T01 will be suspended during this time. For both cohorts, during this time caretakers will continue to monitor their child's symptoms daily with AKL-X01.
During Treatment Phase 2 (Days 57 through 84), participants in Cohort 1 (stimulant) will continue to receive their current stimulant plus the addition of AKL-T01. Participants in Cohort 2 (no stimulant) will just receive AKL-T01. For both cohorts, during this time the caretakers will monitor their child's symptoms daily with AKL-X01.

**Study Design**

- **Study Type:** Interventional (Clinical Trial)
- **Estimated Enrollment:** 203 participants
- **Intervention Model:** Single Group Assignment
- **Intervention Model Description:** The study will enroll participants into one of two cohorts according to stimulant status. Both cohorts will be assigned to AKL-T01.
- **Masking:** None (Open Label)
- **Primary Purpose:** Treatment
- **Official Title:** Software Treatment for Actively Reducing Severity of ADHD as Adjunctive Treatment to Stimulant (STARS-ADHD Adjunctive)

**Estimated Study Start Date:** September 2018  
**Estimated Primary Completion Date:** April 2019  
**Estimated Study Completion Date:** November 2019

### Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
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</table>
| Experimental: AKL-T01  
AKL-T01 digital treatment. | Device: AKL-T01  
AKL-T01 multitasking digital treatment. AKL-T01 multitasking treatment employs perceptual discrimination attention/memory task as well as a continuous motor "driving" task. |

### Outcome Measures

- **Primary Outcome Measures:**
  1. **Change in Impairment Rating Scale (Clinician Report) Overall Impairment; Cohort 1: Stimulant**  
     **[Time Frame: Study Day 0 to Study Day 28]**

     The Impairment Rating Scale (IRS) is an 8-item scale used to measure functioning across 7 different domains including a child's life in school and non-school settings. The scale is administered to a parent by a clinician. Each item is rated on a 7-point scale from 0-6 with 0 indicating no impairment is present to 6 extreme impairment is present. The last questions, question 8, is a rating of the severity of a child's functioning overall.

  2. **Change in Impairment Rating Scale (Clinician Report) Overall Impairment; Cohort 2: Non-Stimulant**  
     **[Time Frame: Study Day 0 to Study Day 28]**

     The Impairment Rating Scale (IRS) is an 8-item scale used to measure functioning across 7 different domains including a child's life in school and non-school settings. The scale is administered to a parent by a clinician. Each item is rated on a 7-point scale from 0-6 with 0 indicating no impairment is present to 6
extreme impairment is present. The last questions, question 8, is a rating of the severity of a child's functioning overall.

Secondary Outcome Measures:

1. Change in ADHD-Rating Scale Total Score; Cohort 1: Stimulant [Time Frame: Study Day 0 to Study Day 28]

   The ADHD-Rating Scale is an 18-item scale assessing the frequency of each ADHD symptom based on DSM-IV criteria. The scale consists of 2 subscales: inattention (9 items) and hyperactivity-impulsivity (9 items). Scoring is based on a 4-point Likert-type severity scale: 0 = none, 1 = mild, 2 = moderate, 3 = severe. The sum of the scores of each of the 18 items comprises the total score.

2. Change in ADHD-Rating Scale Total Score; Cohort 2: Non-Stimulant [Time Frame: Study Day 0 to Study Day 28]

   The ADHD-Rating Scale is an 18-item scale assessing the frequency of each ADHD symptom based on DSM-IV criteria. The scale consists of 2 subscales: inattention (9 items) and hyperactivity-impulsivity (9 items). Scoring is based on a 4-point Likert-type severity scale: 0 = none, 1 = mild, 2 = moderate, 3 = severe. The sum of the scores of each of the 18 items comprises the total score.

3. Clinical Global Impression-Improvement Score; Cohort 1: Stimulant [Time Frame: Day 28]

   The Clinical Global Impression - Improvement Scale (CGI-I) is a single item scale assessing a patient's improvement in overall clinical condition as compared with baseline. The question: "Compared to the patient's condition at admission to the study, this patient's condition is: 1=very much improved since the initiation of treatment; 2=much improved; 3=minimally improved; 4=no change from baseline (the initiation of treatment); 5=minimally worse; 6= much worse; 7=very much worse since the initiation of treatment."

4. Clinical Global Impression-Improvement Score; Cohort 2: Non-Stimulant [Time Frame: Day 28]

   The Clinical Global Impression - Improvement Scale (CGI-I) is a single item scale assessing a patient's improvement in overall clinical condition as compared with baseline. The question: "Compared to the patient's condition at admission to the study, this patient's condition is: 1=very much improved since the initiation of treatment; 2=much improved; 3=minimally improved; 4=no change from baseline (the initiation of treatment); 5=minimally worse; 6= much worse; 7=very much worse since the initiation of treatment."

5. Change TOVA Attention Composite Score (ACS); Cohort 1: Stimulant [Time Frame: Study Day 0 to Study Day 28]

   TOVA ACS is a comparison of the subject's scores based on selected measures that persons with an independent diagnosis of ADHD frequently demonstrated. ACS is calculated from variability, response time (RT), and D' (D Prime) using the following formula: ACS = RT Z score (Half 1) + D' Z score (Half 2) + Variability Z score (Total) + 1.80 where RT is the average time it takes to respond correctly to a target, D' score is a response discriminability score reflecting the ratio of hits to "false alarms", and Variability is a measure of consistency of speed of responding based on the standard deviation of the mean correct response times. API tells how similar the score is to the ADHD profile. A score of less than -1.8
indicates that the subject had similar performance to a normative ADHD population. A lower score indicates a more severe ADHD profile. The calculation for difference in TOVA ACS is ACS at Baseline (Day 0) minus ACS at Day 28.

6. Change TOVA Attention Composite Score (ACS); Cohort 2: Non-Stimulant [ Time Frame: Study Day 0 to Study Day 28 ]

TOVA ACS is a comparison of the subject's scores based on selected measures that persons with an independent diagnosis of ADHD frequently demonstrated. ACS is calculated from variability, response time (RT), and D' (D Prime) using the following formula: ACS = RT Z score (Half 1) + D' Z score (Half 2) + Variability Z score (Total) + 1.80 where RT is the average time it takes to respond correctly to a target, D' score is a response discriminability score reflecting the ratio of hits to "false alarms", and Variability is a measure of consistency of speed of responding based on the standard deviation of the mean correct response times. API tells how similar the score is to the ADHD profile. A score of less than -1.8 indicates that the subject had similar performance to a normative ADHD population. A lower score indicates a more severe ADHD profile. The calculation for difference in TOVA ACS is ACS at Baseline (Day 0) minus ACS at Day 28.

7. Change TOVA Attention Composite Score (ACS); Cohort 1: Stimulant [ Time Frame: Study Day 0 to Study Day 56 ]

TOVA ACS is a comparison of the subject's scores based on selected measures that persons with an independent diagnosis of ADHD frequently demonstrated. ACS is calculated from variability, response time (RT), and D' (D Prime) using the following formula: ACS = RT Z score (Half 1) + D' Z score (Half 2) + Variability Z score (Total) + 1.80 where RT is the average time it takes to respond correctly to a target, D' score is a response discriminability score reflecting the ratio of hits to "false alarms", and Variability is a measure of consistency of speed of responding based on the standard deviation of the mean correct response times. API tells how similar the score is to the ADHD profile. A score of less than -1.8 indicates that the subject had similar performance to a normative ADHD population. A lower score indicates a more severe ADHD profile. The calculation for difference in TOVA ACS is ACS at Baseline (Day 0) minus ACS at Day 28.

8. Change TOVA Attention Composite Score (ACS); Cohort 2: Non-Stimulant [ Time Frame: Study Day 0 to Study Day 56 ]

TOVA ACS is a comparison of the subject's scores based on selected measures that persons with an independent diagnosis of ADHD frequently demonstrated. ACS is calculated from variability, response time (RT), and D' (D Prime) using the following formula: ACS = RT Z score (Half 1) + D' Z score (Half 2) + Variability Z score (Total) + 1.80 where RT is the average time it takes to respond correctly to a target, D' score is a response discriminability score reflecting the ratio of hits to "false alarms", and Variability is a measure of consistency of speed of responding based on the standard deviation of the mean correct response times. API tells how similar the score is to the ADHD profile. A score of less than -1.8 indicates that the subject had similar performance to a normative ADHD population. A lower score indicates a more severe ADHD profile. The calculation for difference in TOVA ACS is ACS at Baseline (Day 0) minus ACS at Day 28.

9. Change in Impairment Rating Scale (Clinician Report) Overall Impairment; Cohort 1: Stimulant [ Time Frame: Study Day 0 to Study Day 84 ]

The Impairment Rating Scale (IRS) is an 8-item scale used to measure functioning across 7 different domains including a child's life in school and non-school settings. The scale is administered to a parent by a
clinician. Each item is rated on a 7-point scale from 0-6 with 0 indicating no impairment is present to 6 extreme impairment is present. The last questions, question 8, is a rating of the severity of a child's functioning overall.

10. Change in Impairment Rating Scale (Clinician Report) Overall Impairment; Cohort 2: Non-Stimulant [Time Frame: Study Day 0 to Study Day 84]

The Impairment Rating Scale (IRS) is an 8-item scale used to measure functioning across 7 different domains including a child's life in school and non-school settings. The scale is administered to a parent by a clinician. Each item is rated on a 7-point scale from 0-6 with 0 indicating no impairment is present to 6 extreme impairment is present. The last questions, question 8, is a rating of the severity of a child's functioning overall.

11. Change in ADHD-Rating Scale Total Score; Cohort 1: Stimulant [Time Frame: Study Day 0 to Study Day 84]

The ADHD-Rating Scale is an 18-item scale assessing the frequency of each ADHD symptom based on DSM-IV criteria. The scale consists of 2 subscales: inattention (9 items) and hyperactivity-impulsivity (9 items). Scoring is based on a 4-point Likert-type severity scale: 0 = none, 1 = mild, 2 = moderate, 3 = severe. The sum of the scores of each of the 18 items comprises the total score.

12. Change in ADHD-Rating Scale Total Score; Cohort 2: Non-Stimulant [Time Frame: Study Day 0 to Study Day 84]

The ADHD-Rating Scale is an 18-item scale assessing the frequency of each ADHD symptom based on DSM-IV criteria. The scale consists of 2 sub-scales: inattention (9 items) and hyperactivity-impulsivity (9 items). Scoring is based on a 4-point Likert-type severity scale: 0 = none, 1 = mild, 2 = moderate, 3 = severe. The sum of the scores of each of the 18 items comprises the total score.

13. Change in ADHD-Rating Scale Total Score; Cohort 1: Stimulant [Time Frame: Study Day 0 to Study Day 56]

The ADHD-Rating Scale is an 18-item scale assessing the frequency of each ADHD symptom based on DSM-IV criteria. The scale consists of 2 subscales: inattention (9 items) and hyperactivity-impulsivity (9 items). Scoring is based on a 4-point Likert-type severity scale: 0 = none, 1 = mild, 2 = moderate, 3 = severe. The sum of the scores of each of the 18 items comprises the total score.

14. Change in ADHD-Rating Scale Total Score; Cohort 2: Non-Stimulant [Time Frame: Study Day 0 to Study Day 56]

The ADHD-Rating Scale is an 18-item scale assessing the frequency of each ADHD symptom based on DSM-IV criteria. The scale consists of 2 subscales: inattention (9 items) and hyperactivity-impulsivity (9 items). Scoring is based on a 4-point Likert-type severity scale: 0 = none, 1 = mild, 2 = moderate, 3 = severe. The sum of the scores of each of the 18 items comprises the total score.

15. Clinical Global Impression-Improvement Score; Cohort 1: Stimulant [Time Frame: Day 84]
The Clinical Global Impression - Improvement Scale (CGI-I) is a single item scale assessing a patient's improvement in overall clinical condition as compared with baseline. The question: "Compared to the patient's condition at admission to the study, this patient's condition is: 1=very much improved since the initiation of treatment; 2=much improved; 3=minimally improved; 4=no change from baseline (the initiation of treatment); 5=minimally worse; 6= much worse; 7=very much worse since the initiation of treatment."

16. Clinical Global Impression-Improvement Score; Cohort 2: Non-Stimulant [Time Frame: Day 84]

The Clinical Global Impression - Improvement Scale (CGI-I) is a single item scale assessing a patient's improvement in overall clinical condition as compared with baseline. The question: "Compared to the patient's condition at admission to the study, this patient's condition is: 1=very much improved since the initiation of treatment; 2=much improved; 3=minimally improved; 4=no change from baseline (the initiation of treatment); 5=minimally worse; 6= much worse; 7=very much worse since the initiation of treatment."

17. Clinical Global Impression-Improvement Score; Cohort 1: Stimulant [Time Frame: Day 56]

The Clinical Global Impression - Improvement Scale (CGI-I) is a single item scale assessing a patient's improvement in overall clinical condition as compared with baseline. The question: "Compared to the patient's condition at admission to the study, this patient's condition is: 1=very much improved since the initiation of treatment; 2=much improved; 3=minimally improved; 4=no change from baseline (the initiation of treatment); 5=minimally worse; 6= much worse; 7=very much worse since the initiation of treatment."

18. Clinical Global Impression-Improvement Score; Cohort 2: Non-Stimulant [Time Frame: Day 56]

The Clinical Global Impression - Improvement Scale (CGI-I) is a single item scale assessing a patient's improvement in overall clinical condition as compared with baseline. The question: "Compared to the patient's condition at admission to the study, this patient's condition is: 1=very much improved since the initiation of treatment; 2=much improved; 3=minimally improved; 4=no change from baseline (the initiation of treatment); 5=minimally worse; 6= much worse; 7=very much worse since the initiation of treatment."

19. Change in Impairment Rating Scale (Clinician Report) Overall Impairment; Cohort 1: Stimulant [Time Frame: Study Day 0 to Study Day 56]

The Impairment Rating Scale (IRS) is an 8-item scale used to measure functioning across 7 different domains including a child's life in school and non-school settings. The scale is administered to a parent by a clinician. Each item is rated on a 7-point scale from 0-6 with 0 indicating no impairment is present to 6 extreme impairment is present. The last questions, question 8, is a rating of the severity of a child's functioning overall.

20. Change in Impairment Rating Scale (Clinician Report) Overall Impairment; Cohort 2: Non-Stimulant [Time Frame: Study Day 0 to Study Day 56]

The Impairment Rating Scale (IRS) is an 8-item scale used to measure functioning across 7 different domains including a child's life in school and non-school settings. The scale is administered to a parent by a clinician. Each item is rated on a 7-point scale from 0-6 with 0 indicating no impairment is present to 6
extreme impairment is present. The last questions, question 8, is a rating of the severity of a child's functioning overall.

21. Change in Test of Silent Reading Efficiency and Comprehension (TOSREC); Cohort 1: Stimulant
   [ Time Frame: Study Day 0 to Study Day 28 ]
   Using the participant- and time-appropriate form; Cohort 1: Stimulant

22. Change in Test of Silent Reading Efficiency and Comprehension (TOSREC); Cohort 2: Non-Stimulant
   [ Time Frame: Study Day 0 to Study Day 28 ]

23. Change in Test of Silent Reading Efficiency and Comprehension (TOSREC); Cohort 1: Stimulant
   [ Time Frame: Study Day 0 to Study Day 84 ]

24. Change in Test of Silent Reading Efficiency and Comprehension (TOSREC); Cohort 2: Non-Stimulant
   [ Time Frame: Study Day 0 to Study Day 84 ]
   Using the participant- and time-appropriate form; Cohort 2: Non-Stimulant

25. Change in Mathematics Fluency and Calculation Test; Cohort 1: Stimulant [ Time Frame: Study Day 0 to Study Day 28 ]

26. Change in Mathematics Fluency and Calculation Test; Cohort 2: Non-Stimulant [ Time Frame: Study Day 0 to Study Day 28 ]

27. Change in Mathematics Fluency and Calculation Test; Cohort 1: Stimulant [ Time Frame: Study Day 0 to Study Day 84 ]

28. Change in Mathematics Fluency and Calculation Test; Cohort 2: Non-Stimulant [ Time Frame: Study Day 0 to Study Day 84 ]

Other Outcome Measures:

1. Parental Report of AKL-X01 Usage [ Time Frame: Study Day 0 to Study Day 84 ]
   Compliance of app usage as compared to expected usage of 5 days per week

2. Participant Experience Questionnaire [ Time Frame: Day 84 ]
   Descriptive questionnaire about the participant's experience with the study device

3. Parent/Caregiver Experience Questionnaire [ Time Frame: Day 84 ]
   Descriptive questionnaire about the parent's/caregiver's experience with the study device

4. Parent/Caregiver Preference Questionnaire [ Time Frame: Day 84 ]
   Descriptive questionnaire about the parent's/caregiver's preference of ADHD treatment for their child
5. Participant demographics [ Time Frame: Day 84 ]

Descriptive analyses

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 14 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Male or female, ages 8 years 0 months to 14 years 9 months (inclusive), at the time of parental informed consent.
2. Confirmed ADHD diagnosis (primarily inattentive or combined subtype), at Screening based on DSM-V criteria and established via the MINI-KID administered by a trained clinician.
   Note: Co-morbid diagnoses on the MINI-KID are acceptable provided that ADHD is the primary diagnosis and the co-morbid diagnoses will not confound study data (per the Investigator's judgment).
3. Currently experiencing sub-optimal treatment of ADHD, based upon results of Clinical Global Impression-Severity score.
4. Impairment Rating Scale (Parent Report) score of ≥ 3 at Screening.
5. Ability to follow written and verbal instructions (English), as assessed by the PI and/or study coordinator.
6. Estimated IQ score > 80 as assessed by the Kaufmann Brief Intelligence Test, Second Edition (KBIT-II).
7. Ability to comply with all testing, requirements, study procedures, and availability for the duration of the study.
8. Provision of signed and dated parental informed consent form and assent form.
9. Participant's parent and/or caregiver has access any of the following Apple™ or Android™ smart phone and/or mobile devices (for accessing AKL-X01 application): Apple iPhone 6, 6+, 7, 8, 10; Android Samsung Galaxy S7, S7 Edge, S8, S8+, S9, S9+; Android Samsung Note 8; Android LG G6, G7, V30, K20. Apple mobile devices must be running iOS 11.2+. Android mobile devices must be running Nougat or Marshmallow.
10. For Cohort 1 (stimulant), participant must be stable** on stimulant medication, at an approved FDA dose, for ≥ 30 days prior to enrollment (may also be one stimulant plus a booster, provided that the dose is stable and does not change throughout the course of the trial).
   **Note: Medication stability is defined as:
   o Moderate response on stimulant, but still room for improvement
   o Dose unchanged within past 30 days, but other doses have been tried previously without improvement
   o Currently taking stimulant, but parent and/or caregiver wishes not to increase dosage for any reason
   o Taking consistent stimulant dose on weekdays, but not on weekends
11. For Cohort 2 (non-stimulant), participant must be stable off stimulant medication for ≥ 30 days prior to enrollment.
Exclusion Criteria:

1. Current, controlled (requiring a restricted medication) or uncontrolled, comorbid psychiatric diagnosis, based on MINI-KID and subsequent clinical interviewing, with significant symptoms including but not limited to:
   1. post-traumatic stress disorder
   2. psychosis
   3. bipolar illness
   4. pervasive developmental disorder
   5. severe obsessive compulsive disorder
   6. severe depressive
   7. severe anxiety disorder
   8. conduct disorder
   9. other symptomatic manifestations that in the opinion of the Investigator may confound study data/assessments.

Participants with clinical history of learning disorders will be allowed to participate, provided the disorder does not impact their ability to participate in the trial based on PI judgment.

2. Participants who are currently treated with a non-stimulant medication for ADHD (i.e., atomoxetine, clonidine, guanfacine).

3. Participants diagnosed with ADHD Hyperactive-Impulsive subtype, based upon score on the MINI-KID interview.

4. Participants showing no room for improvement, or those refractory to non-intensive ADHD treatment.

5. Initiation within the last 4 weeks from the time of consent of behavioral therapy. Participants who have been in behavior therapy consistently for more than 4 weeks may participate provided their therapy frequency and intensity is unchanged during the course of the study. Participants planning on changing or initiating behavior therapy during the course of the study will be excluded.

6. 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.

7. Motor condition (e.g., physical deformity of the hands/arms; prostheses) that prevents playing the digital treatment as reported by the parent or observed by the investigator.

8. Recent history (within the past 6 months) of suspected substance abuse or dependence.

9. History of seizures (exclusive of febrile seizures), or significant motor or vocal tics, including but not limited to Tourette's Disorder.

10. Has participated in a clinical trial within 90 days prior to Screening.

11. Diagnosis of or parent-reported color blindness (Confirmed in-clinic via ICBT)

12. Uncorrected visual acuity (confirmed in-clinic, via ability of participant to play the game, at Screening)

13. Regular use of psychoactive drugs (non-stimulant) that in the opinion of the Investigator may confound study data/assessments.

14. Any other medical, behavioral, or developmental condition that in the opinion of the investigator may confound study data/assessments.

15. Has a sibling also enrolled/currently participating in the same study. Siblings may participate in the study sequentially, but not at the same time.

16. Has previously been randomized in a study of Akili's videogame-like digital treatment.

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): NCT03649074

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Sponsors and Collaborators
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Investigators
Principal Investigator: Scott Kollins, PhD  Duke Clinical Research Institute
Principal Investigator: Daniel Laskowitz, MD  Duke Clinical Research Institute

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Responsible Party: Akili Interactive Labs, Inc.
ClinicalTrials.gov Identifier: NCT03649074  History of Changes
Other Study ID Numbers: 001S-A
First Posted: August 28, 2018  Key Record Dates
Last Update Posted: August 28, 2018
Last Verified: August 2018

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Undecided

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: Yes
Device Product Not Approved or Cleared by U.S. FDA: Yes
Pediatric Postmarket Surveillance of a Device Product: No
Product Manufactured in and Exported from the U.S.: No

Keywords provided by Akili Interactive Labs, Inc.:
ADHD

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity  Mental Disorders
Attention Deficit and Disruptive Behavior Disorders  Central Nervous System Stimulants
Neurodevelopmental Disorders  Physiological Effects of Drugs