MANUFACTURER
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These Instructions for Use were last updated in August 2023
Part Number: 5015 Revision C

REF

Endeavor OTC™

INSTRUCTIONS FOR USE

REVISION C

CONTENTS

Labels and Symbols

CAUTION: Pay special attention to the following details

Manufacturer

Reference Part Number

Lot Number

Consult Instructions for Use

Customer Support

We're here to help.

Ensuring your satisfaction with our products is our priority.

For answers to common questions related to purchases, treatment recommendations, technical issues, or general information check out our **Frequently Asked Questions**.

For anything else please email us at

support@endeavorotc.com

Instructions For Use

CAUTIONS

Please follow all of your mobile device manufacturer's instructions for the safe operation of your mobile device. For example, this may include appropriate volume settings, proper battery charging, not operating the device if damaged, and proper device disposal. Contact your mobile device manufacturer for any questions or concerns that pertain to your device.

If you experience frustration, emotional reaction, dizziness, nausea, headache, eye-strain, or joint pain while playing EndeavorOTC, pause the treatment. If the problem persists contact your health care provider. If you experiences a seizure stop the treatment and contact your health care provider.

EndeavorOTC is not a substitute for your medication.

U.S. FDA ENFORCEMENT DISCRETION POLICY

EndeavorOTC is made available under the U.S. Food and Drug Administration's current Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. EndeavorOTC has not been cleared or authorized by the U.S. Food and Drug Administration for its indications. It is recommended that patients speak to their health care provider before starting EndeavorOTC treatment.

For additional resources relating to ADHD treatment, or if your ADHD symptoms and/or impairments are not improving, contact your health care provider. If you are experiencing a medical emergency, please dial 911.

INDICATIONS FOR USE

EndeavorOTC is a digital therapeutic indicated to improve attention function, ADHD symptoms, and quality of life in adults 18 years of age and older with primarily inattentive or combined-type ADHD. EndeavorOTC utilizes the same proprietary technology underlying EndeavorRx, a prescription digital therapeutic indicated to improve attention function in children ages 8-12.

SIDE EFFECTS

No serious adverse events have been reported in any of our clinical studies. Of 921 participants in trials evaluating the use of EndeavorOTC and supporting EndeavorRx authorization, 65 participants (7.1%) experienced treatment-related adverse events (probable, likely). Associated adverse events included frustration, headache, dizziness, emotional reaction, nausea, and aggression. All adverse events were generally mild/moderate and transient, and no subject reported lasting or irreversible effects after discontinuation.

NOTE: EndeavorOTC and EndeavorRx were previously known as AKL-T01 during the clinical investigations.

NOTES

EndeavorOTC may not be appropriate for patients with photo-sensitive epilepsy, color blindness, or physical limitations that restrict use of a mobile device; patients should consult with their health care provider.

Compatible Devices

ANDROID DEVICE MINIMUM SPECIFICATIONS

Android™ OS version	9.0
Storage	32 GB of storage space
Memory	3 GB of RAM
Network Infrastructure	WiFi
Example Devices	**Samsung Galaxy S10™, Samsung Tab A8, and similar or later models.**

iOS DEVICE MINIMUM SPECIFICATIONS

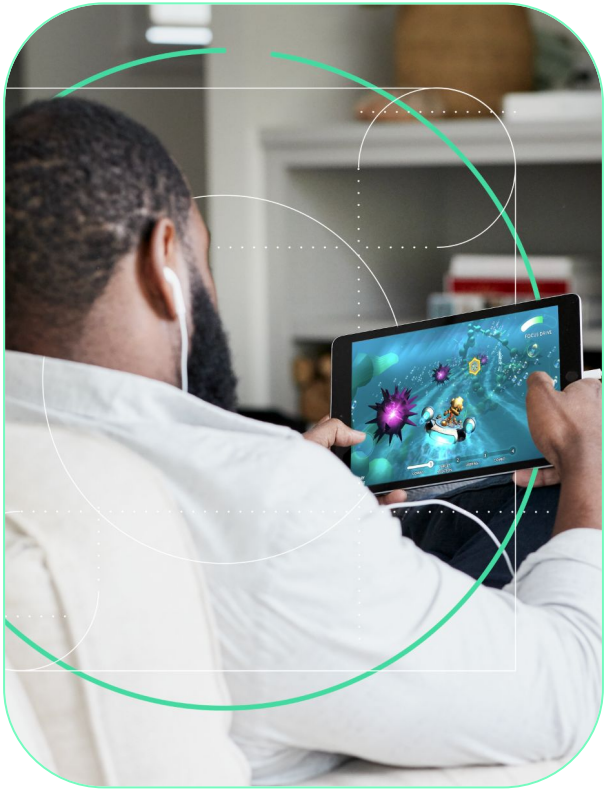
iOS™ version	15.0	iPadOS® version	15.0
Storage	16 GB of storage space		
Memory	2 GB of RAM		
Network Infrastructure	WiFi		
Example Devices	**iPad® Mini 5, iPhone® 11 and later models.**		

For more information on device compatibility, please visit the EndeavorOTC.com FAQ. Refer to the section *Technical* > *"What devices are compatible with EndeavorOTC?"*

To easily determine if your device is compatible, download EndeavorOTC from your app store and open it. If you cannot find it in your app store, your device may not be compatible.

Core Technologies

Patented, proprietary technology designed to target key neural attentional control systems in the brain.



SELECTIVE STIMULUS MANAGEMENT

The Selective Stimulus Management Engine (SSME™) is a proprietary & patented technology that presents specific sensory stimuli and simultaneous motor challenges designed to target key neural systems in the brain related to attentional control.

SSME implements specific closed-loop algorithms that adapt real-time and between treatment sessions to automatically adjust the difficulty level for a personalized treatment experience. The algorithms enable second by second monitoring of patient progress, and continuously challenge each patient to an optimized level, encouraging them to improve their performance.

Product Description

EndeavorOTC is a digital, non-drug treatment delivered through an action video game that was shown to improve attention function in adults with ADHD.
EndeavorOTC treatment is used on a mobile device. See page 7 for compatible devices.
EndeavorOTC is different from other action video games that you might play. The treatment programmed into the game was designed to challenge attentional control during gameplay, requiring focus and flexibility to manage multiple tasks at the same time.

The proprietary technology (AKL-T01) underlying EndeavorOTC and EndeavorRx has been supported by the following clinical studies:

- A study of of 221 adults with ADHD (either on or off ADHD medication), where AKL-T01 was used for a 6-week treatment period and showed improvements in attention function, attention-related ADHD symptoms and impairments, and quality of life.
- A study of of 162 adolescents with ADHD (either on or off ADHD medication), where AKL-T01 was used for a 4-week treatment period and showed improvements in attention function, ADHD symptoms, and related impairments.
- A study of 348 children with ADHD (not receiving ADHD medication), where AKL-T01 was used for a 4-week treatment period and showed improvements in attention function (as measured by computer-based testing) and attention-related ADHD symptoms and impairments.
- A study of 206 children with ADHD (on stimulant medication or not receiving any ADHD medication), where AKL-T01 was used for a 4-week period, followed by a treatment pause of one month and a subsequent second 4-week treatment period. Improvements in attention-related ADHD symptoms and impairments were similar in magnitude to those seen in other studies and further improved with the second treatment period in children on or off ADHD medication.
- Three separate studies of 40, 20 and 19 children with ADHD, where AKL-T01/ AKL-T02 was used for a 4-week treatment period and showed improvements in attention measures and attention-related ADHD symptoms.

NOTE: EndeavorOTC and EndeavorRx were previously known as AKL-T01 during the clinical investigations. AKL-T02, while retaining the same user interface and SSME therapeutic engine as AKL-T01, has adapted gameplay difficulty intended to increase user engagement in an autism spectrum disorder population.

Getting Started with EndeavorOTC

RECOMMENDATIONS BEFORE YOU START TREATMENT

It is recommended that the mobile device be stored **password protected** to reduce the risk of unauthorized access.

Be sure that the mobile **device is fully charged** before use and that the **device's audio system is functioning properly** and the **audio is set at an appropriate level**.

GETTING STARTED WITH TREATMENT

For best results, we recommend playing the game approximately 25 minutes a day, 5 days a week. Our clinical study showed that the best results come with this routine for 6 weeks, although many participants showed substantial improvements in attention and clinical functioning with less play time. To assist in understanding daily progress, the app displays a 25 minute countdown timer on the home screen that resets at the start of each treatment day. The 25 minutes only counts gameplay time, referred to as Mission Minutes, and does not include extra time you may spend in the game browsing non-mission areas like the Costume Store and the Space Farm.

Try to fit EndeavorOTC into your routine and make it a habit. You can make use of reminders in the game or any other tools you use for managing your schedule.

Minimize distractions during each treatment with EndeavorOTC. We recommend turning off device reminders and notifications, using EndeavorOTC in a quiet room with headphones, and turning off other mobile devices and televisions. Find a comfortable place where you can use EndeavorOTC daily, ideally seated in an upright position in a well-lit room with minimal glare on the device.

It is best if the patient adjusts the field of view and avoids using the device too close to their eyes. It is recommended to turn on the blue light filter on the device if administered during nighttime, but also recommended not to play right before bedtime to avoid risk of potential reduction in sleep quality.

Understand that by design, EndeavorOTC will be **challenging** (and sometimes frustrating) to play. Try and give each treatment of EndeavorOTC your full attention and effort to help ensure the best treatment results.

During a treatment session **it is OK to occasionally take a break** from treatment for a few minutes if needed, for example to avoid excess eye strain or fatigue.

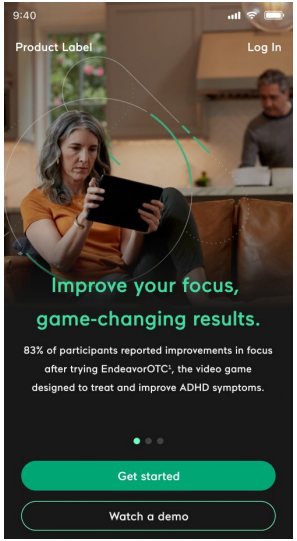
Operating Instructions

LAUNCH & LOGIN

Tap the application icon on the mobile device to start. If you already have an existing Akili account, tap the **"Log In"** button and log in with your existing Akili Account using your email address and password. At this point you will be granted access to treatment if you have an active subscription. If you do not have an active auto-renewing subscription you will be prompted to purchase one after login.

If you do not have an Akili account, tap the "Get Started" link on the initial screen to create an Akili Account and sign up for an auto-renewing subscription.

To open the EndeavorOTC product label, tap the "Product Label" button found in the upper left corner of the screen. Here you can find helpful information like the app version number and a link to the EndeavorOTC Instructions for Use.



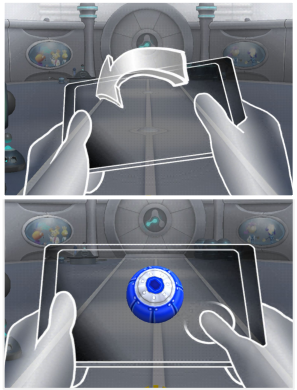
MANIPULATING THE DEVICE

EndeavorOTC features 3 primary actions: 1) **Steering**, 2) **Tapping**, and 3) **Steering** and **Tapping** at the same time (multitasking).

To **Steer**, tilt the mobile device left and right. Try to hold the mobile device with both hands to help with the steering and tapping.

To **Tap** on a target, touch the right half of the mobile device screen using your thumb. This touch can be anywhere on the right side of the screen – it does not have to be directly on the flying target nor the "target" button.

In addition to the primary actions above, you will be able to unlock **Boosts** through the course of play. Equipped **Boosts** can be activated by tapping the left side of the screen and have a variety of effects in the racing experience.

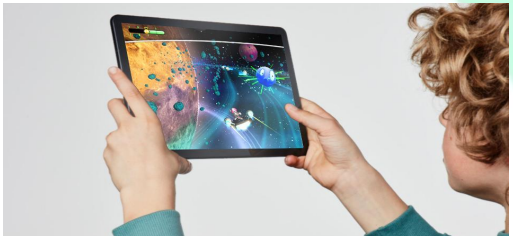


EndeavorOTC Daily Treatment

When using EndeavorOTC, the goal is to successfully **Steer** the character through a course while driving over power zones or avoiding obstacles, and **Tap** the right side of the screen to collect only the correct targets when they appear while ignoring all other targets. At the beginning of the **Mission**, you will be shown multiple targets and asked to collect only specific types of targets - for example, you may be shown red, green, and blue targets and will be asked to only tap the red targets.

Each course completed from start to finish is an individual **Mission**, and time spent within those Missions are known as **Mission Minutes**. The technology behind EndeavorOTC has been shown to benefit those who play up to 25 minutes a day. For this reason, we've included a 25 **Mission Minute** countdown in the game, intended to help you maximize your time.

There are many separate **Worlds** to unlock and explore as you progresses through treatment.

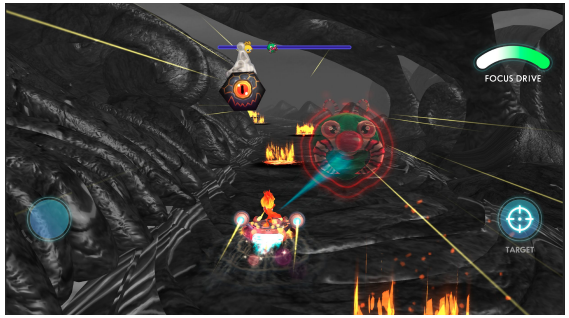


Playing **EndeavorOTC** can fit into your daily routine. The more you play, the better your results.

Playing the game every day for six weeks can improve your attention and other functions that makeup your ability to focus. At six weeks, we recommend a short recovery period to evaluate your progress and prepare for the next dose, as the game is intentionally challenging. Then, resume play for another six weeks to further enhance your progress.

Unlike an action video game, there is no way to "win" EndeavorOTC. The game continuously challenges the patient by adjusting the gameplay to maintain a consistent level of difficulty relative to how well they are playing the game. As long as you are playing consistently and trying your best, you are engaging with the treatment as intended.

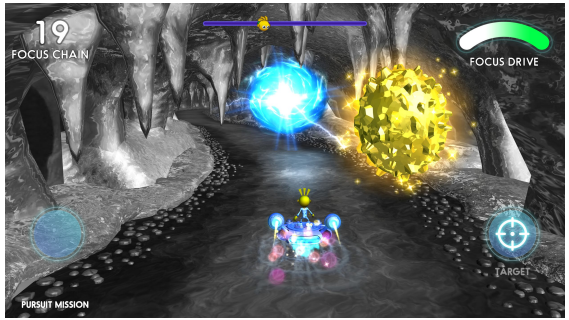
Daily Mission Minutes



The technology behind EndeavorOTC has been shown to benefit those who play up to 25 minutes a day. For this reason, we've included a 25 Mission Minute countdown in the game, intended to help you maximize your time. **Mission Minutes** can be tracked on the Galaxy Map screen. When **Mission Minutes** reach zero you will receive an in-game reward for your efforts, and will no longer be able to participate in new **Missions** until the next day. This makes sure EndeavorOTC is used in a manner consistent with the intended treatment schedule and prevents overuse.

During each **Mission**, you will **Steer** your character through a course, moving through gates and/or avoiding obstacles, and **Tap** to collect targets when they appear. With successful tapping and steering, you can catch **Mystic Creatures** and earn rewards.

The hover pod's capture ray will automatically lock on when you get close to the **Mystic Creature**. If you remain locked on for a few seconds, you will capture the creature and earn a **Mystic Gem**. **Mystic Gems** can be hard to get – and each one will be harder to get than the previous one.



When the hover pod locks on to a creature and captures it, EndeavorOTC has recognized that you have reached a new ability level in your play.

After collecting 15 **Mystic Gems** a new **World** will be unlocked.

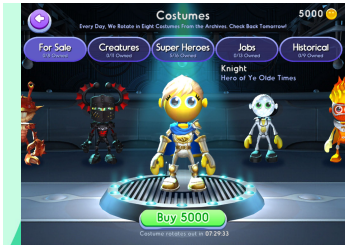
EndeavorOTC was designed to, on average, take around 4 weeks to unlock all worlds, but actual speed of progression may vary across patients. Independent of your progress, it is important that you engage regularly with the treatment.

Once all worlds are unlocked, you can revisit your favorite **World** to play and beat your previous scores. In addition, you can continue to complete **Quests**, unlock costumes, and upgrade your **Space Farm**.

Game User Interface

SUMMARY SCREEN

When you finish a **Mission**, a summary screen will appear displaying the important goals, progress, and rewards achieved.



STORE

You can use the rewards you have earned to unlock your desired costumes in the game store. As you progress you can choose the costume you like the best, or collect them all!

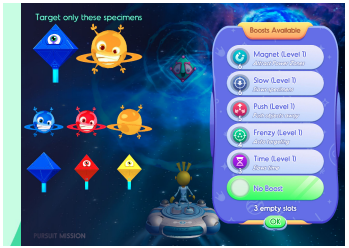
GALAXY MAP

The **"main menu"** provides a visual representation of overall progress through the many environments across the **Galaxy** of EndeavorOTC. From here, you can access the costume store, visit your **Space Farm**, view your **Quests**, and choose an environment in your current **World** to play next! In the bottom-right of this screen you can see how many **Mission Minutes** you have left to play for the day.

Game User Interface (cont.)

SPACE FARM

As you play, you will capture different kinds of **Mystic Creatures**. Captured creatures live in the **Space Farm** and each kind of creature gets its own special dwelling. These dwellings generate **Boosts** that you can use during gameplay. You can upgrade a **Mystic Creature's** dwelling by collecting more of that creature. Build better dwellings to get better **Boosts**!



BOOST EQUIP SCREEN

Prior to each **Pursuit Mission**, you will be able to equip a **Boost** to help them in the race. There is a limit on how many they can bring with them based on their **Player Level**, and can only equip from the current inventory of **Boosts**. New **Boosts** are generated each day after the first **Mission**!

Pausing and Exiting Treatment

PAUSE AND RESUME TREATMENT

Each daily treatment can be paused at any time by tapping the upper-left corner of the screen.
Tap **"Resume"** to continue the treatment. *Note: There are built-in rest periods between missions.*

EXIT AND END TREATMENT

When a daily session is completed, the EndeavorOTC application can be closed on your device.
After your treatment subscription to EndeavorOTC expires, the treatment will become automatically disabled.

Please contact your health care provider to discuss your experience and the best treatment plan for you.

Mobile Device Security

DEVICE SECURITY RECOMMENDATIONS

EndeavorOTC software incorporates state of the art security features in order to protect the data of users. Users should configure the mobile device they're using to play EndeavorOTC with the following security settings in order to maximize their security.

- Configure the mobile device with a strong passcode, pin code, Face ID, or Touch ID.
- Configure the mobile device to automatically lock after a period of inactivity.
- Configure the mobile device with USB Restricted Mode enabled.
- Configure the mobile device with two-factor authentication enabled.
- Configure the mobile device to show notifications only when the device is unlocked.
- Only connect the device to secure wireless networks with a passcode and encryption.
- Configure the mobile device backup with encryption enabled.
- Keep the mobile device operating system and EndeavorOTC application up to date with the latest available versions.
- In order to maintain manufacturer security protections do not jailbreak or root the device.

Troubleshooting

We're here to help.
support@endeavorotc.com

Q. The EndeavorOTC application does not start properly.

Ensure that the mobile device is connected to WiFi.

Ensure that the mobile device meets the minimum specifications outlined in the list of compatible devices section.

Ensure there is enough free storage space on your device to download and operate the application.

Q. My email or password is not accepted by the EndeavorOTC application.

Double-check you have entered the text correctly.

Ensure that the mobile device is connected to WiFi during login and account registration.

Q. I can't play all of my Mission Minutes.

If played right around midnight in your local time, some of the Mission Minutes might count for next day's gameplay (for example, starting the gameplay at 11.57pm and finishing at 12.03am). This issue can be alleviated by playing all missions in the same calendar day.

Q. The application unexpectedly quits, stops responding, or won't open.

Follow your device manufacturer instructions to force quit the application (then open it again), restart your device, check for system updates or reinstall the application, if necessary.

Q. The application keeps getting interrupted by notifications.

Follow your device manufacturer instructions to turn off or modify notifications prior to playing EndeavorOTC.

Clinical Research

For Licensed Health Care Providers

Note: EndeavorOTC was previously known as AKL-T01 during the clinical investigations.

Clinical Research

CLINICAL ENDPOINT ACRONYMS

AA-QoL: Adult ADHD Quality of Life Score

ADHD-RS: ADHD Rating Scale (total score)

ADHD-RS-Hyperactive: ADHD-RS hyperactivity-impulsivity subscale

ADHD-RS-Inattentive: ADHD-RS inattention subscale

BRIEF: Behavior Rating Inventory of Executive Function

CAARS-S:S Conners' Adult ADHD Rating Scales–Self Report: Short Version

CGI-I: Clinical Global Impression - Improvement

IRS: Impairment Rating Scale to measure ADHD-related impairment

TOVA®: Test of Variables of Attention

TOVA API: TOVA Attention Performance Index (also known as TOVA ACS)

TOVA ACS: TOVA Attention Comparison Score (formerly known as TOVA API)

TOVA RT Mean H1: TOVA Reaction Time Mean (first half of the test)

TOVA RT Var: TOVA Reaction Time Variability (total test)

Clinical Research (cont.)

INTRODUCTION

Seven clinical studies in over 900 children, adolescents, and adults with ADHD have been used in support of EndeavorOTC. These studies include 1 pivotal trial of adults 18 years of age and older with ADHD (STARS-ADHD-Adult); 1 pivotal study of adolescents aged 13-17 years of age with ADHD (STARS-ADHD-Adolescent); 3 studies in children between the ages of 8-14 years of age with ADHD (STARS-ADHD, STARS-Adjunct and ADHD-POC) and 2 pilot studies in ADHD with different comorbidities (Sensory Processing Disorder and Autism Spectrum Disorder).

Clinical Research (cont.)

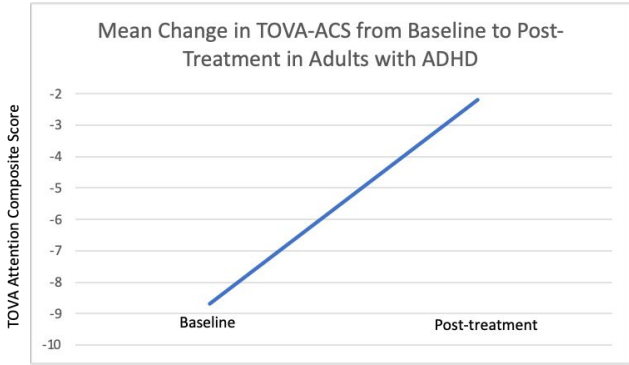
STARS-ADHD Adult[1]

The STARS-ADHD Adult study used to generate data to support AKL-T01 enrolled 221 adults, 18 years and older, with ADHD for a six-week treatment period.

Study Design: An open label single arm 6 week trial of AKL-T01 in adults. 18 years and older, with ADHD, primarily inattentive or combined-type ADHD (either on or off ADHD medication) with a TOVA ACS baseline score ≤ -1.8, conducted at 14 sites in the USA. The 221 participants were asked to engage with the treatment for approximately 25 minutes per day, 5 days per week, for 6 weeks.

Objectives: The primary endpoint was mean change in TOVA ACS from pre- to post-intervention (baseline to 6 weeks). Secondary endpoints were mean changes in ADHD-RS (Total score and Inattentive subscore). Exploratory endpoints were AAQoL total score, AAQoL Life Productivity Subscore, CAARS-S:S and TOVA results other than the API.

Results: The primary endpoint was achieved; mean change from baseline on the TOVA ACS was 6.46 (p=0001). Adults using AKL-T01 also showed significant improvement in their ADHD symptoms, as measured by the clinician-administered Attention Deficit Hyperactivity Disorder Rating Scale-5 (ADHD-RS). Following treatment, participants in the study showed significant improvement on both the inattention subscale and total score of the ADHD-RS (p<0.0001 for both). A prespecified responder analysis also showed that 32.7% of all participants in the study demonstrated at least a 30% reduction in total scores on the ADHD-RS. Nearly three-quarters (72.5%) of adults reported at least some improvement in their quality of life as measured by the validated Adult ADHD Quality of Life Scale (AAQoL), and nearly 50 percent (45.8%) of adults met a prespecified threshold for clinically meaningful improvement.



Safety and Compliance: Overall, 11(5%) of the participants in the trial reported a treatment-emergent adverse device event, most commonly nausea (1.8%) and headache (1.4%). There were no serious adverse device events.

[1]Akili, Data on file.

Clinical Research (cont.)

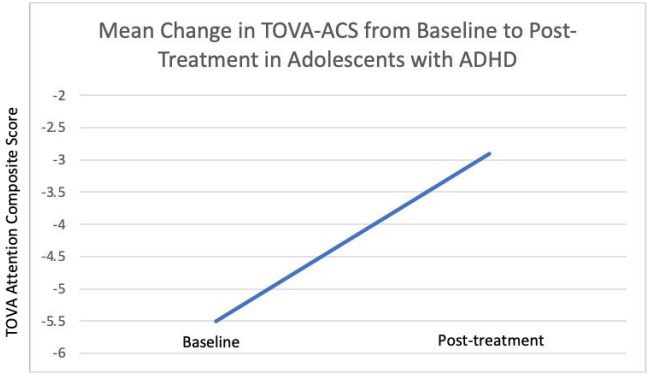
STARS-ADHD Adolescent[1]

The STARS-ADHD Adolescent study used to generate data to support AKL-T01 enrolled 162 adolescents ages 13-17 with ADHD for a four week treatment period.

Study Design: An open label single arm 4 week trial of AKL-T01 in adolescents ages 13-17 with ADHD (either on or off ADHD medication) with a TOVA ACS baseline score ≤ -1.8. The 162 participants were asked to engage with the treatment for approximately 25 minutes per day, 5 days per week, for 6 weeks.

Objectives: The primary endpoint was mean change in TOVA ACS from pre- to post-intervention (baseline to 6 weeks). Secondary endpoints were mean changes in ADHD-RS (Total score and Inattentive subscore) Exploratory endpoints were ADHD-related impairment and TOVA results other than the API.

Results: AKL-T01 demonstrated a statistically significant improvement in the TOVA ACS of sustained and selective attention from baseline after one month of treatment ($p<0.0001$), the study's predefined primary efficacy outcome. Nearly two-thirds (66%) of adolescents met the prespecified definition of clinical response on the TOVA-ACS and nearly a quarter (24.7%) moved into the non-clinical, or normative, range. Following treatment, participants in the study showed significant improvement on both the inattention subscale and total score of the ADHD-RS ($p<0.0001$ for both). A prespecified responder analysis also showed that 27.1% of all participants in the study demonstrated at least a 30% reduction in total scores on the ADHD-RS, a finding similar to the STARS-ADHD trial in children with ADHD (24%). Statistically significant improvements were also observed for parent and child ratings of attention improvement, as well as parent ratings of function across a number of domains, including peer relationships, academic functioning, behavioral functioning, homework functioning, and self-esteem.



Safety and Compliance: Overall, 4 (2.5%) participants experienced a treatment-emergent adverse device event (3 decreased frustration tolerance, 1 headache; all mild or moderate). There were no serious adverse device events.

1 Mercaldi C, Suh M, Childress A, Higgins N, Kollins S. A Single Arm Pivotal Trial to Assess the Efficacy of AKL-T01, a Novel Intervention Designed to Improve Attention, in Adolescents diagnosed with Attention Deficit Hyperactive Disorder (ADHD). Poster presented at: American Society for Clinical Psychopharmacology Annual Meeting; May 31, 2023; Miami, FL.

Clinical Research (cont.)

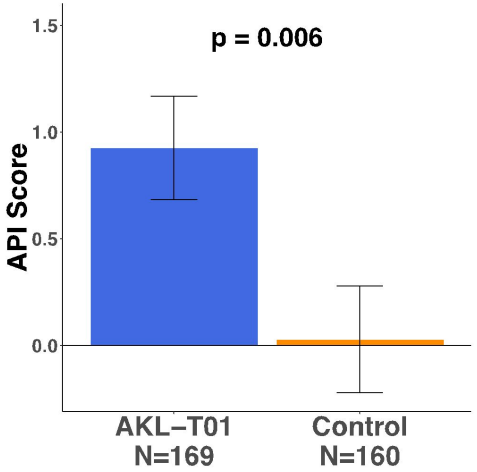
STARS-ADHD Pivotal Study[1]

Study Design: A randomized, double-blind, parallel-group, 4-week, controlled trial of AKL-T01 in children aged 8-12 years old with ADHD (not taking ADHD medications) and TOVA API baseline scores of ≤ −1.8, conducted at 20 sites in the USA. 348 subjects were randomly assigned to receive AKL-T01 (n=180) or control (n=168) for approximately 25 minutes per day, 5 days per week, for 4 weeks.

Objectives: The primary endpoint was mean change in TOVA API from pre- to post-intervention (baseline to 4 weeks). Secondary endpoints were mean changes in ADHD-RS (Total, Inattentive, Hyperactive), IRS, CGI-I, BRIEF (working memory, inhibit).

Results: The primary endpoint was achieved, mean change from baseline on the TOVA API was 0.93 in the AKL-T01 group versus 0.03 in the control group (p=0.006). The secondary endpoint within-group (baseline to post-treatment) changes were all significantly improved, and several mean changes numerically favored AKL-T01 over control (ADHD-RS Total, ADHD-RS Inattentive, IRS), however there was no statistically meaningful difference in a non-parametric analysis of the 7 secondary parental or clinical rating scales (Adjusted p=0.34 to 1.00). There were two notable responder analyses (56% of parents indicated the treatment improved their child's attention and 48% were shown to improve their ADHD-related impairment as reported in the IRS).

Safety and Compliance: There were no serious adverse events or discontinuations. Treatment-related adverse events were mild and included frustration (5 [3%] of 180), headache (3 [2%] of 180) and emotional reaction (2 [1%] of 180). Patient compliance was a mean of 83 (83%) of 100 expected sessions played (SD, 29.2 sessions).



Endeavor OTC

[1] *Kollins et al, Lancet Digital Health, 2020*

Clinical Research (cont.)

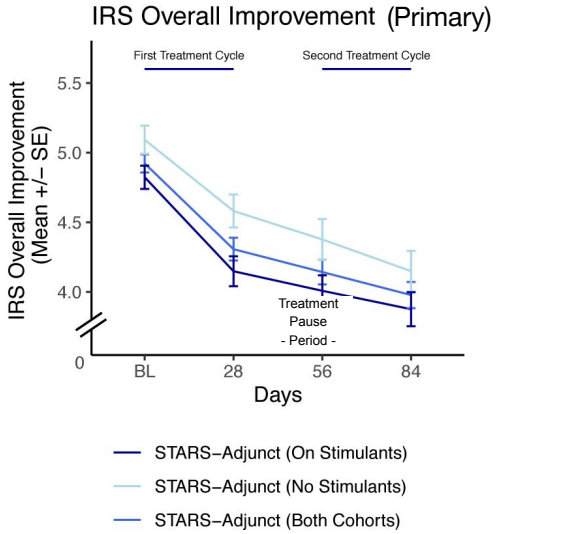
STARS-Adjunct Study[1]

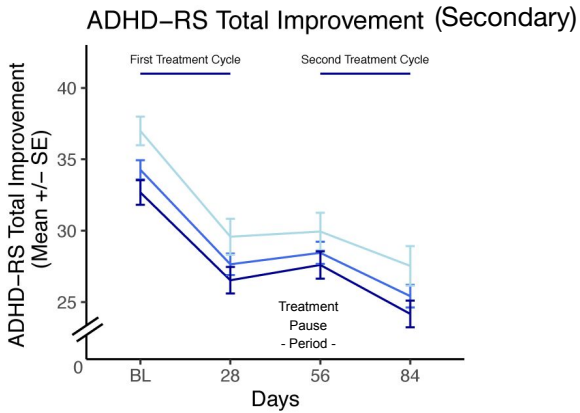
Study design: A multicenter, 12-week, open-label study of AKL-T01 in 206 children aged 8-14 years with ADHD, consisting of 2 cohorts: 1) Subjects currently treated with ADHD medication (On Stimulants, n=130) and 2) Subjects not on any ADHD medication (No Stimulants, n=76). Subjects were required to have an IRS score ≥3 at baseline and both cohorts received AKL-T01 for approximately 25 minutes per day, 5 days per week, over two 4 week treatment periods, separated by a 4-week treatment pause. There was no digital control in this study.

Objectives: The primary endpoint was change from baseline to day 28 on the Impairment Rating Scale (IRS), a measurement of ADHD-specific impairment. Key secondary and exploratory measures included changes from baseline to day 28 and day 84 on ADHD symptoms (ADHD-RS), the clinical global impairment -improvement score (CGI-I) and measures of patient/parent preference and experience.

Results: After the first treatment month (day 28), IRS overall severity score was significantly improved for both the On Stimulants (-0.7, p<0.001) and No Stimulants (-0.5, p<0.001) cohorts compared to baseline. ADHD-RS (Total, Inattentive and Hyperactive subscales) and CGI-I were also significantly improved for both cohorts compared to baseline at day 28. IRS, ADHD-RS, and CGI-I all further improved with an additional treatment month (baseline to day 84).

Safety and Compliance: 37 (18%) subjects experienced a device-related adverse events (AE). The most common device-related AEs were frustration (27 [13.1%] of 206), headache (4 [1.9%] of 206), and irritability (3 [1.5%] of 206). All device-related AEs were either mild or moderate in severity. There were 3 discontinuations due to AEs (all frustration). No serious device-related AEs occurred during this study.





[1] *Kollins et al, npj Digital Medicine, 2021*

Clinical Research (cont.)

ADHD Proof of Concept Study[1]

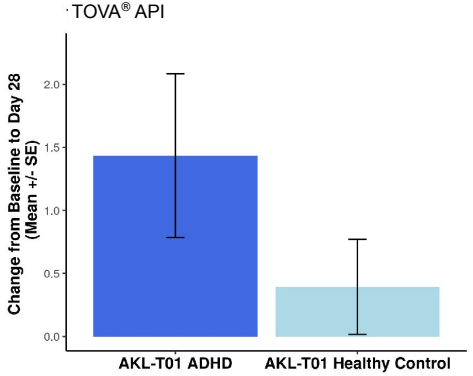
Study Design: A 4-week, open-label study of AKL-T01 in children aged 8-12 years old, comparing 40 children with ADHD to 40 neurotypical children (healthy controls). The ADHD group were required to have an in-clinic diagnosis of ADHD, not be taking ADHD medications and have an ADHD-RS total score of ≥24 at baseline (healthy controls were required to have an ADHD-RS ≤13). The study was conducted at 3 sites in the US.

Treatment: Subjects were instructed to complete approximately 25 minutes of AKL-T01 per day, 5 days per week for 4 weeks.

Objectives: To explore whether subjects demonstrated improvements in attention function, as measured by TOVA and other measures.

Results: Improvements were observed on TOVA API for the ADHD group (mean change=-1.43, p=0.033, d=0.35). There was no significant change for the healthy control group (mean change= -0.39, p=0.30, d=017).

Safety and Compliance: There were no treatment-related adverse events. 84% of treatment sessions were completed.



[1] *Davis et al., PLOS One, 2018*

Clinical Research (cont.)

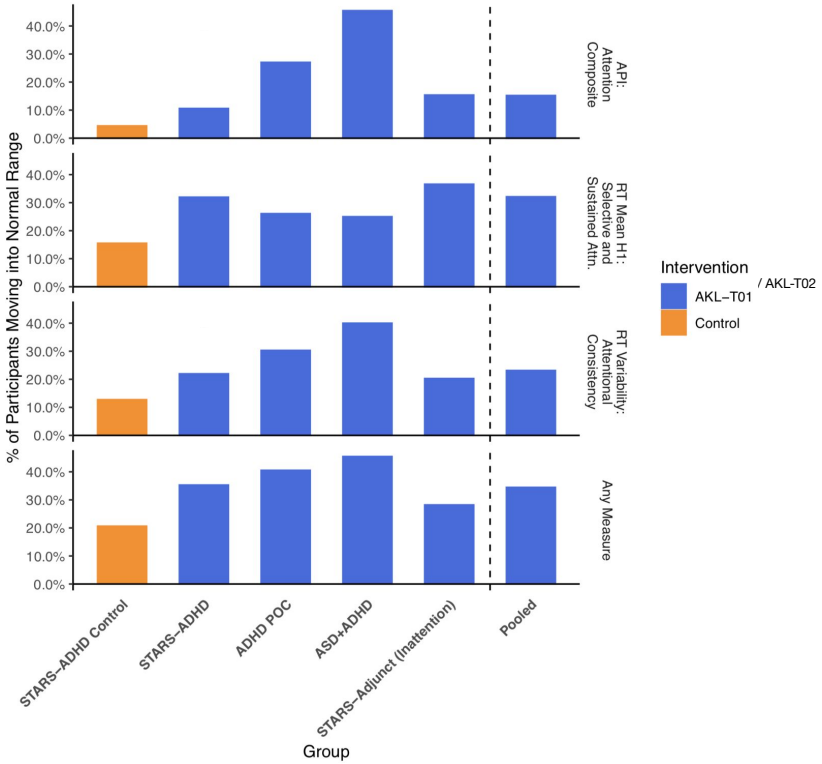
ADDITIONAL STUDIES

ADHD + Sensory Processing Disorder (SPD)[1]: a pilot study of AKL-T01 in children ages 8-12 with SPD only (n=13), SPD+ADHD (n=20) and Healthy Controls (n=24). There was improvement in objective attention measures comparable to STARS-ADHD and the SPD+ADHD group showed a decrease in parent-reported ADHD-inattentive symptoms (-4.5 / SD=4.7).

ADHD + Autism Spectrum Disorder (ASD)[2]: a randomized, double-blind, controlled study of AKL-T02 (which retains the same SSME therapeutic engine as AKL-T01) in 19 children ages 9-13 years old with ASD and comorbid ADHD, 11 randomized to AKL-T02 and 8 to digital control. AKL-T02 group improved in TOVA API (mean change=1.86, p=0.12, d=0.72) while the Control group worsened (mean change= -0.82, p=0.55, d=0.35). AKL-T02 group improved in ADHD symptoms (ADHD-RS-Total, mean change= -6.72, p=0.003, d=2.03). Both groups had high compliance with their intervention. There was one non-serious adverse event (decreased frustration tolerance) in the AKL-T02 group.

OBJECTIVE ATTENTION ACROSS STUDIES[3]

The percentage of children moving into the normative range on objective measures of attention (TOVA API, RT Mean H1 and RT Var) is between 10-45% across all clinical studies. Overall, 34.5% of children moved into the normative range on at least one of these objective measures of attention after 4 weeks of treatment with AKL-T01/AKL-T02.



[1] *Anguera et al., PLOS One, 2017*
[2] *Yerys et al., J Autism Dev Disord, 2019*
[3] *Data on File, Akili, 2020*

Clinical Research (cont.)

SIDE EFFECTS

No serious adverse events have been reported in any of our clinical studies. Of 921 participants in trials supporting the technology behind EndeavorOTC and EndeavorRx (AKL-T01), 65 participants (7.1%) experienced treatment-related adverse events (probable, likely). Associated adverse events included frustration, headache, dizziness, emotional reaction, nausea, and aggression. All adverse events were generally transient, and no subject reported lasting or irreversible effects after discontinuation.

NOTE

EndeavorOTC may not be appropriate for patients with photo-sensitive epilepsy, color blindness, or physical limitations that restrict use of a mobile device; consult with your health care provider.