



Frequently Asked Questions

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Akili Interactive

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We're here to help.

Akili Assist is available for questions regarding the use of Endeavor and to offer technical assistance.

Available: Monday–Friday (excluding National Holidays)

Hours of Operation: 9:00 am – 5:00 pm Eastern Timezone (EST/EDT)

Website: AkiliAssist.com

Phone: 1-844-AKILI-IQ (1-844-254-5447)

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General

What is the Endeavor™ Treatment?

The Endeavor treatment is digital therapeutic software intended for the treatment of attention function in children with Attention Deficit Hyperactivity Disorder (ADHD).

What is the Endeavor treatment indicated/used for?

The Endeavor treatment is indicated to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type ADHD who have a demonstrated attention issue. Patients who engage with the Endeavor treatment demonstrate improvements in a digitally assessed measure (T.O.V.A.®) of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity. The Endeavor treatment should be considered for use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs, which further address symptoms of the disorder.

The Endeavor treatment is not a substitute for your child's ADHD medication. You should review the Instructions for Use before using the Endeavor treatment. The Instructions for Use can be found [here](#).

Has the Endeavor treatment been studied in clinical trials?

The Endeavor treatment has been evaluated in over 600 children with ADHD across 5 clinical studies. The Endeavor treatment has been shown to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type ADHD who have a demonstrated attention issue.

What are the results of clinical trials with Endeavor?

The Endeavor treatment has been evaluated in over 600 children with ADHD across 5 clinical studies:

- A study of 348 children with ADHD, where the Endeavor treatment was used for a 4-week treatment period and showed improvements in attention measures and attention-related ADHD symptoms and behaviors
- A study of 206 children with ADHD, where the Endeavor treatment was used for two 4-week periods and showed that an additional treatment period resulted in further improvements in attention-related ADHD symptoms and behaviors
- Three separate studies of 40, 20 and 19 children with ADHD, where the Endeavor treatment was used for a 4-week treatment period and showed improvements in attention measures and attention-related ADHD symptoms

General

What is the Endeavor Treatment System™ care program?

To get the most out of your experience, we suggest using the Endeavor Treatment System™ care program, which includes:

- Endeavor™ treatment for your child
- ADHD Insight™ behavior tracking app for you, the caregiver, to take an active role in your child's treatment program by monitoring changes and improvements
- Akili Assist™ support for you, the caregiver, as your direct line and trusted partner to guide you through your treatment experience

How should the Endeavor treatment be used?

Children are expected to interact with the Endeavor treatment for 30-minutes per day, five days per week over the course of a one-month treatment cycle. The benefits seen in clinical trials of improving attention require full engagement and commitment throughout a one-month treatment cycle.

At the end of the one-month treatment cycle, your child may benefit from another one-month treatment cycle.

Our clinical trials indicate that children may take a break (of up to 4 weeks) after a one-month treatment cycle and gain further benefit from a second one-month treatment cycle.

If your child has experienced any side effects from using the Endeavor treatment, or if you have any questions about the benefit of continuing with the Endeavor treatment, please contact your child's healthcare professional to discuss your child's experience and determine if additional treatment cycles are warranted.

You should consult with your child's healthcare professional and review the Instructions for use before using the Endeavor treatment. You can find the Instructions for Use [here](#).

Do I have to consult with my child's healthcare professional before obtaining the Endeavor treatment?

Yes, you should contact your child's healthcare professional before using the Endeavor treatment. When registering for the Endeavor treatment, you must acknowledge your child's healthcare professional is aware that your child will be using the Endeavor treatment.

General

Has the Endeavor treatment been cleared by the Food and Drug Administration (FDA)?

The Endeavor treatment has not been cleared by the FDA.

The current release of the Endeavor treatment is enabled by new guidance from FDA for certain low-risk clinically-validated digital health devices for psychiatric conditions in response to the COVID-19 public health emergency. During this public health emergency, the Endeavor treatment is available without a prescription.

My child does not have ADHD, but I think the Endeavor treatment might be right for him/her. Can you advise?

The Endeavor treatment is indicated for children ages 8-12 years old with primarily inattentive or combined-type ADHD who have a demonstrated attention issue. If your child does not have ADHD, then the Endeavor treatment is not available for him/her right now.

The Endeavor treatment is delivered via a digital screen. Should I be fearful of screen time risks?

We understand that screen time can be of concern to parents and physicians. We are aligned with the American Academy of Pediatrics in its policy on media use in school-age children and adolescents and the recommendation to set consistent limits on hours per day on media.

The Endeavor treatment is limited to 25-30 minutes of screen exposure per day. This is the time it takes your child to finish the daily treatment's five missions. The Endeavor treatment will automatically lock after each daily treatment session is completed.

During a treatment cycle, be sure to let your child know that it is OK to occasionally take a break from treatment for a few minutes in order to avoid excess eye strain or fatigue.

General

Will my child experience any side effects from using Endeavor?

The Endeavor treatment is delivered through a video game. In order to support the game's engagement and fun components, the Endeavor gameplay sometimes includes flashing lights and altering light patterns. This is common among video games played by children.

There were no serious adverse events seen in any clinical trials of Endeavor. Of 538 participants using Endeavor (AKL-T01) in clinical trials, 50 participants (9.3%) experienced treatment-related adverse events. Endeavor associated adverse events included frustration (6.1%), headache (1.3%), dizziness (0.6%), emotional reaction (0.4%), nausea (0.4%), and aggression (0.2%).

A very small percentage of individuals who play video games may experience epileptic seizures or blackouts when exposed to certain light patterns or flashing lights. Playing video games may trigger epileptic seizures or blackouts in these individuals. These conditions may also trigger previously undetected epilepsy or seizures in persons who have no prior history of epilepsy or seizures. If your child, or anyone in your family, has an epileptic condition or has had seizures of any kind, please consult your child's physician before using the Endeavor treatment.

The Endeavor treatment may not be appropriate for children with color blindness or physical limitations that restrict use of a mobile device. If your child has any of these conditions, please consult with your child's physician before using the Endeavor treatment.

If your child experiences health problems while using the Endeavor treatment (such as dizziness, lightheadedness, nausea, altered vision, eye or muscle twitches, eye discomfort or pain, joint discomfort or pain, loss of awareness, disorientation, seizures, convulsions or any involuntary movements), stop the treatment and contact your child's physician before resuming use of the Endeavor treatment.

If your child experiences any side effects related to using the Endeavor treatment (such as frustration, headache, dizziness, emotional reaction, nausea or aggression), stop the treatment and contact your child's physician before resuming use of the Endeavor treatment.

Does my data remain safe and private if my child uses the Endeavor treatment?

We understand how important it is to protect your privacy. Akili uses industry standard privacy and security measures to protect your child's health data. You can find the full Privacy Policy for the Endeavor treatment on our website: [GetEndeavor.com](https://www.getendeavor.com/privacy-policy).

Do I have to pay for the Endeavor treatment?

For a limited time, we are providing three-month access to those who qualify at no cost.

General

I have questions in general about my child using the Endeavor treatment. What should I do?

You can reach out to us via www.akiliassist.com or by calling 1-844-AKILI-IQ (1-844-254-5447). In the meantime, you can also access our Instructions for Use from our website: GetEndeavor.com. You should contact your child's healthcare professional before using the Endeavor treatment.

How It Works

What is the clinical benefit of the Endeavor treatment?

The Endeavor treatment has been studied across five clinical trials, which included more than 600 children diagnosed with ADHD. The Endeavor treatment has been shown to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type ADHD who have a demonstrated attention issue.

Why does my child need to play 5 days a week, 25 minutes a day? Is it possible to play less or more?

Children are expected to interact with the Endeavor treatment for 30-minutes per day, five days per week over the course of a one-month treatment cycle. The benefits seen in clinical trials of improving attention require full engagement and commitment throughout a minimum of a one-month treatment cycle.

At the end of the one-month treatment cycle, your child may benefit from another one-month treatment cycle. Our clinical trials indicate that children may take a break (of up to four weeks) after a one-month treatment cycle and gain further benefit from a second one-month treatment cycle. If your child has experienced any side effects from using the Endeavor treatment, or if you have any questions about the benefit of continuing with the Endeavor treatment, please contact your child's healthcare professional to discuss your child's experience and determine if additional treatment cycles are warranted.

My child just finished the first month. Now what?

At the end of the one-month treatment cycle, your child may benefit from another one-month treatment cycle. Our clinical trials indicate that children may take a break (of up to four weeks) after a one-month treatment cycle and gain further benefit from a second one-month treatment cycle. If your child has experienced any side effects from using the Endeavor treatment, or if you have any questions about the benefit of continuing with the Endeavor treatment, please contact your child's healthcare professional to discuss your child's experience and determine if additional treatment cycles are warranted.

If appropriate, you and your child will receive a code to renew treatment for the next month.

How It Works

What type of improvement can I expect to see?

Children with ADHD who engage with the Endeavor treatment demonstrate improvements in a digitally assessed measure (TOVA) of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity.

To date, the Endeavor treatment has been evaluated in over 600 children with ADHD across 5 clinical studies:

- A study of 348 children with ADHD, where the Endeavor treatment was used for a 4-week treatment period and showed improvements in attention measures and attention-related ADHD symptoms and behaviors
- A study of 206 children with ADHD, where the Endeavor treatment was used for two 4-week periods and showed that an additional treatment period resulted in further improvements in attention-related ADHD symptoms and behaviors
- Three separate studies of 40, 20 and 19 children with ADHD, where the Endeavor treatment was used for a 4-week treatment period and showed improvements in attention measures and attention-related ADHD symptoms

How can I review my child's progress?

You can track your child's game progress in the Endeavor treatment by reviewing the summary screen which displays goals, progress and rewards achieved.

The [ADHD Insight](#) behavior tracking app is available to you whether or not your child is using Endeavor. With the ADHD Insight behavior tracking app, you can track your child's behaviors and assess overall progress. It is available for you to download in the Apple and Google Play stores.

Consult your child's healthcare professional to discuss how to best monitor the Endeavor treatment.

Technical

Is an internet connection required to play?

Internet or network connectivity is not required to use the Endeavor treatment, but it is required to download, register, activate and start treatment. Once your child begins a one-month treatment cycle, he or she can use the Endeavor treatment online or offline. We recommend your child play the Endeavor treatment while connected to WiFi so that the product can stay in sync with important updates and data.

Can my child play the Endeavor treatment on an Android device?

At this time, the Endeavor treatment is only available on iOS devices that meet our minimum requirements.

What are the iOS device minimum requirements?

You can review the iOS device minimum requirements in our Instructions for Use [here](#).

Can my child pause during sessions?

Yes, each daily treatment can be paused at any time by tapping the upper-left corner of the screen. Note that there are built-in rest periods between sessions (every four-five minutes on average).

If I have problems activating my code. what should I do?

We are happy to help! You can reach out to us with any technical difficulties via www.AkiliAssist.com or call 1-844-AKILI-IQ (1-844-254-5447).

Do I need to sit with my child while they play Endeavor?

That is a decision entirely up to you, but it is not necessary. However, we do recommend that you designate a suitable place free from distractions for your child to play, as well as a time of day. It is fine to experiment with the best time to engage with the Endeavor treatment. It is recommended not to play right before bedtime to avoid risk of potential reduction in sleep quality.

Support

If I have questions about the Endeavor treatment, who do I contact?

You may contact us at www.AkiliAssist.com or 1-844-AKILI-IQ (1-844-254-5447).

Can you send me some information I can share with my healthcare professional?

Yes, we are more than happy to share information about the Endeavor treatment with you and/or your child's healthcare professional. Please have your child's healthcare professional email us at info@akiliinteractive.com with their question.

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