

EndeavorRx ADHD Video Game: A CADDRA Information Sheet

What is the name of the therapy and who had developed it?

EndeavorRx (AKL-T01) is designed by Akili Interactive Labs, a Boston-based company

Who is the digital therapy prescribed for, and how?

- EndeavorRx is a prescription-only treatment delivered through a video game that is indicated to improve attention in children with ADHD ages 8-12 years old
- Children use treatment by steering an avatar through a course dotted with obstacles and collecting targets to earn rewards and advance to the next level in play;
- The treatment requires quick reaction time and decision-making and increases in difficulty in response to the player's skills;
- It is designed to directly target and activate neural systems through the presentation of sensory stimuli and motor challenges to improve cognitive functioning
- Children should use the treatment 25-30 minutes per day without interruption, five days a week, over the course of a one-month treatment cycle;

Is the digital therapy designed as a stand-alone treatment for ADHD?

- No, the game is indicated to be used alongside other treatments, such as clinician-directed therapy, medication and educational programs

What evidence did the FDA review before authorizing EndeavorRx?

- The FDA reviewed five clinical studies that included more than 600 children that evaluated, among other things, whether participants demonstrated improvements in attention function.
- The primary outcome measured in the majority of the studies was mean change in T.O.V.A. Attention Performance Index (API) from pre-intervention to post-intervention.
- The most significant randomized, controlled study was published in The Lancet Digital Health and involving 348 participants. It showed that after playing EndeavorRX for five days a week for four weeks, a third of the children no longer had a measurable attention deficit on at least one measure of objective attention.
- Further, in clinical studies, about half of parents in the study saw a clinically meaningful change in their child's day-to-day impairments after one month of treatment with EndeavorRx; this increased to 68% after a second month of treatment;

- Improvements in ADHD impairments following a month of treatment with EndeavorRx were maintained for up to a month.
- There were no serious adverse events or discontinuations reported. Treatment-related adverse events were mild and included frustration and headache.

Interested in seeing what the digital therapy looks like?

- Watch this [Good Morning America video](#).

Is the use of digital treatments for ADHD common in the U.S.?

- No, in fact EndeavorRx was reviewed through FDA's De Novo premarket review pathway, a regulatory pathway for low to moderate risk devices of a new type. Its clearance creates a new class of digital therapeutics and it is the first-of-its-kind non-drug treatment option for ADHD.

Is the video game treatment available in Canada?

- No. A company spokesperson says they intend to expand outside of the U.S., but the timing of that expansion is not currently known.

CADDRA's viewpoint:

- Therapeutic use of digital technology to improve cognitive functioning is innovative and exciting. The primary outcome for the majority of these studies was the TOVA - Attention Performance Index. It should be noted that use of a digital outcome to look at impact of a digital intervention raises the question of how this treatment will translate to real life improvement in symptoms and function.
- Since ADHD symptoms did not separate from placebo, and the Impairment Rating Scale did, we need to know more about what Endeavor is treating.
- These randomized controlled trials used a very rigorous placebo of a Word Game – and still came out statistically significant. This implies Endeavor has a specific effect over and above time, expectations, and practice. Further research is needed to find out what that effect is.
- While this treatment has potential to help children with cognitive difficulties and represents something truly 'new' which can be effective with minimal risk. However, EndeavorRx should not be considered as a substitute for well researched medication and psychosocial treatments for ADHD.