

Improving Objective Measures of Attention in Test of Variables of Attention (TOVA) into Normative Ranges with AKL-T01, a Digital Treatment for Attention in Pediatric ADHD

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Across 4 studies and 1 month of treatment with **AKL-T01** over one-third of children with ADHD and impaired attention no longer fell into the impairment range on at least 1 objective measure of attention: global attention, selective attention, sustained attention, or attentional consistency on the TOVA

BACKGROUND

Attention problems

- have detrimental effects on children with ADHD
- often persist despite medication management

AKL-T01 is a digital treatment designed to improve attention function delivered through a video game interface.

A key endpoint across AKL-T01 trials was the Test of Variables of Attention (TOVA®), an FDA-cleared objective test of attention.

Clinically meaningful response on the TOVA:

moving from an impaired into a normative range, ie. performing consistent with an age- and gender-matched non-ADHD normative sample.

Research Question:

How many children moved into the normative range on TOVA objective attention measures after 4 weeks of AKL-T01 treatment across our clinical trials in pediatric ADHD?

METHODS

TOVA objective measures of attention:

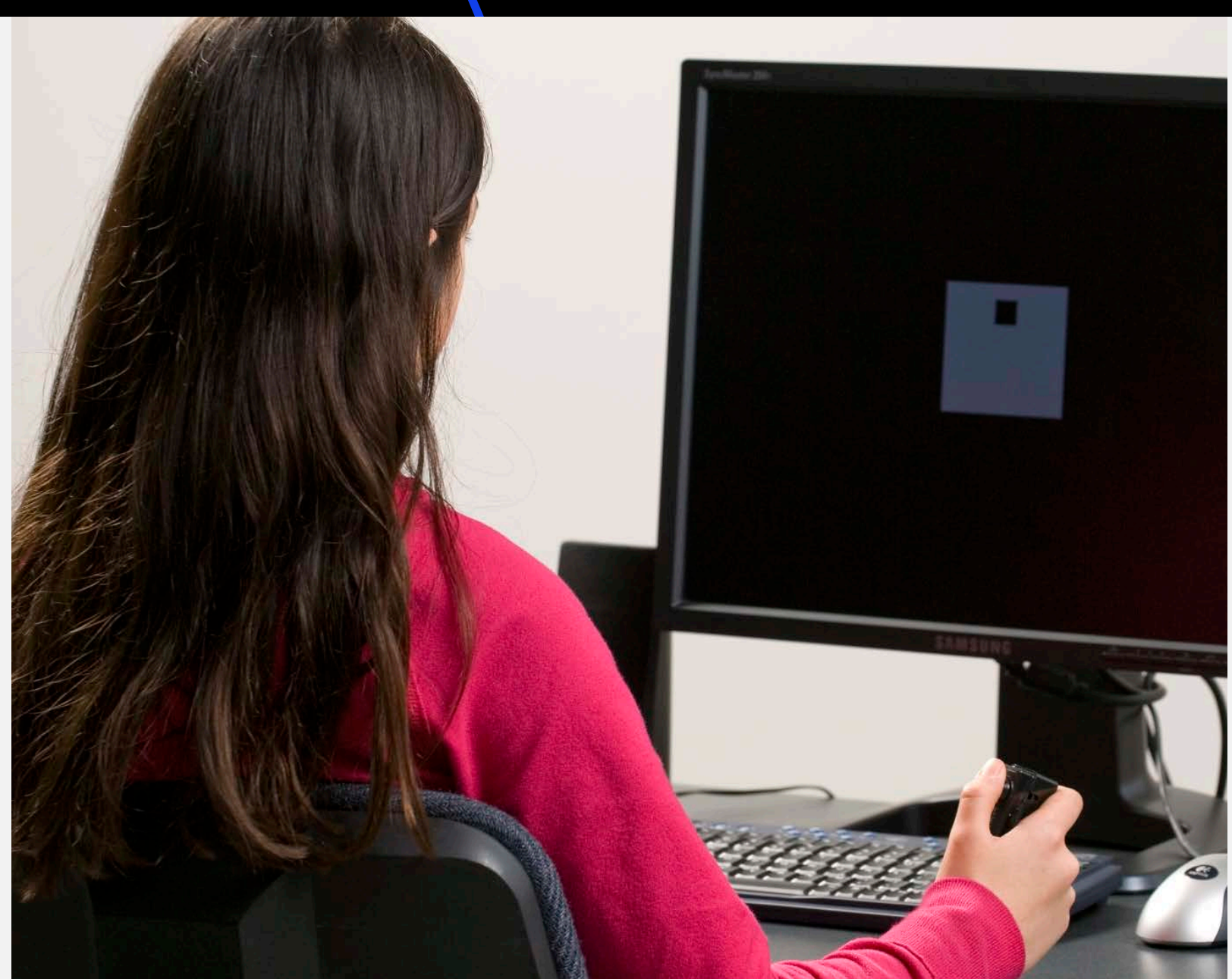
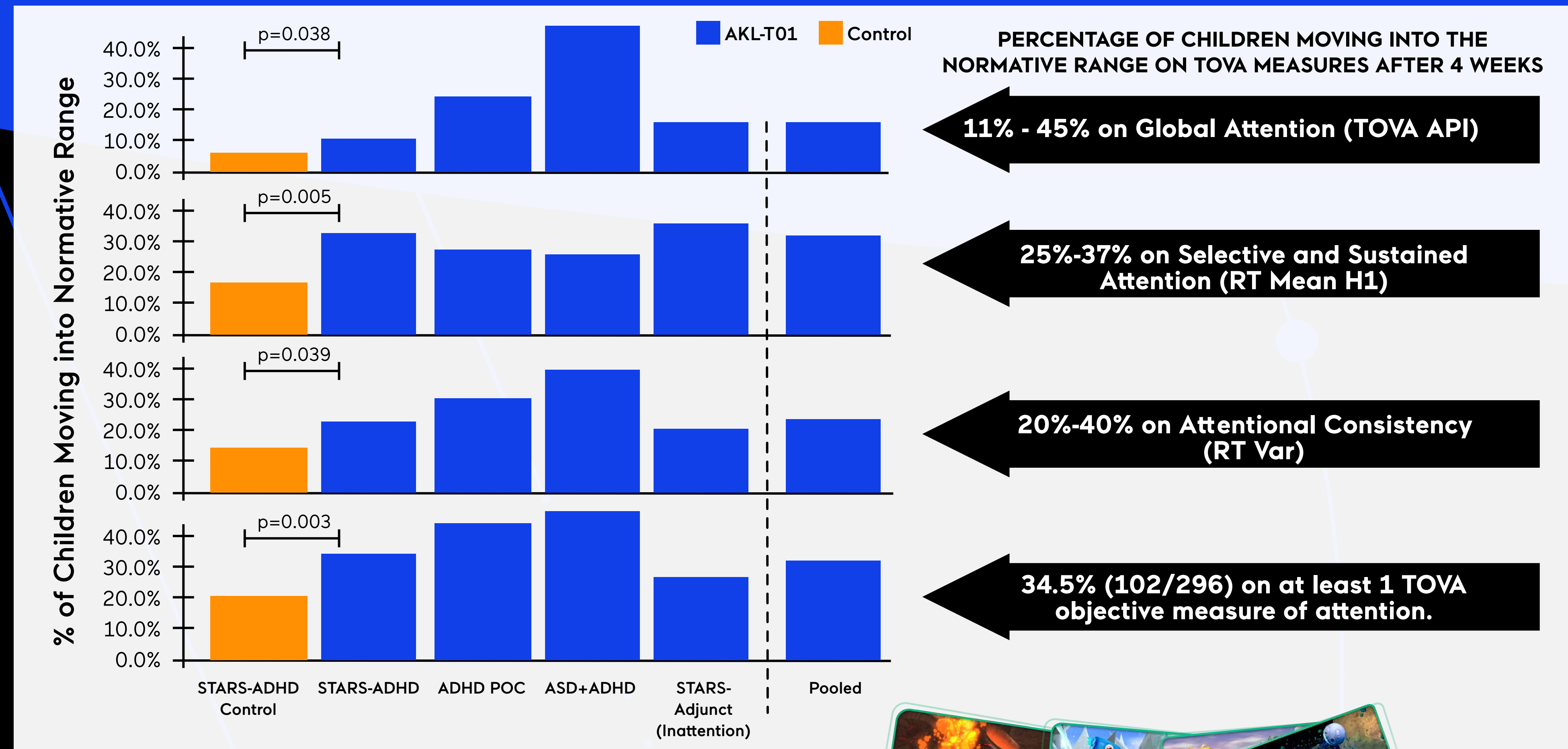
- Attention Performance Index (API): Composite score measuring global attention
- Reaction Time Mean First Half (RT Mean H1): Selective and sustained attention
- Reaction Time Variability (RT Var): Attentional consistency

Normative range:

API: a score of ≥ 0
 RT Mean H1/RT Var: within 1 SD of TOVA norms¹

Analyses included 296 children aged 8 to 15 years old with ADHD and TOVA impairment from 4 clinical trials: STARS-ADHD RCT, ADHD POC, ASD+ADHD, STARS-Adjunct (Inattention group with TOVA API ≤ 1.8 at baseline).

RESULTS



Clinical trials:	ADHD POC ²	STARS-ADHD ³	ASD Pilot ⁴	Stars-Adjunct ⁵
Population	ADHD	ADHD	Autism + ADHD	ADHD
Intervention arms	2-arms: AKL-T01 in ADHD and Healthy Controls	2-arms: AKL-T01 versus digital control	2-arms: AKL-T01 versus digital control	2-arms: AKL-T01 On Stimulants, AKL-T01 No Stimulants
N (ADHD)	80 (40)	348 (348), 180 randomized to AKL-T01	19 (19), 11 randomized to AKL-T01	206 (206), STARS-Adjunct Inattention group: 80
Age	8-12 yrs	8-12 yrs	9-15 yrs	8-13 yrs
On ADHD Medication	0%	0%	15.80%	63%

CONCLUSIONS

Across 4 studies after 4 weeks of treatment with AKL-T01: **34.5% of children with ADHD and impaired attention no longer fell into the impaired range on at least 1 objective measure of attention:** global attention, selective attention, sustained attention, or attentional consistency on the TOVA.

Movement into normative ranges was relatively consistent across studies.

REFERENCES

- ¹TOVA clinical manual, Greenberg, 2018.
- ²ADHD POC: Davis, N.O. et al., "Proof-of-Concept Study of an at-Home, Engaging, Digital Intervention for Pediatric ADHD," PLoS One 13, no. 1 (2018): e0189749.
- ³STARS-ADHD: Kollins et al., "A Novel Digital Intervention for Actively Reducing Severity of Paediatric ADHD (STARS-ADHD): A Randomised Controlled Trial," The Lancet Digital Health 2, no. 4 (April 1, 2020): e168-78.
- ⁴ASD Pilot: Yerys et al., "Brief Report: Pilot Study of a Novel Interactive Digital Treatment to Improve Cognitive Control in Children with Autism Spectrum Disorder and Co-Occurring ADHD Symptoms," Journal of Autism and Developmental Disorders 49, no. 4 (2019): 1727-37.
- ⁵STARS-Adjunct: not published yet

DISCLOSURES

RDM: Is or was on the Advisory Board and received Research Support
 A.J. and J.L. are employed at Akili interactive and may own stock options