

# AKL-T01, a Digital Treatment for Pediatric ADHD as an Adjunct to Stimulant Medication: Response Rates With Repeat Administration

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# AKL-T01 - a digital treatment for inattention in ADHD - improved ADHD-related impairment in 2 out of 3 children with ADHD, independent of their ADHD medication status after 2 treatment months.

## Background

### STARS-Adjunct trial goals:

1. What is the effect of combining AKL-T01 with stimulant medication?
2. What is the effect of a second treatment month in children on and off stimulant medication?

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

Previous STARS-ADHD RCT:  
 Significant responder rate of 48% on ADHD-related impairment (Impairment Rating Scale, IRS) compared to digital control (37%) in children with ADHD but without ADHD medication who used AKL-T01 for 1 month.

## Results

### Responder rates in ADHD-related impairment and symptoms

Outcome Measure	Response Rate Definition	AKL-T01 Response Rate: STARS-Adjunct						STARS-ADHD RCT
		No Stimulants		On Stimulants		Both Cohorts		
		Day 28	Day 84	Day 28	Day 84	Day 28	Day 84	
Impairment Rating Scale (IRS)	% children with $\geq 1$ improvement on IRS Overall Severity	40.5%	69.7%	55.5%	68.1%	50%	68.3%	48%
ADHD total symptoms (ADHD-RS Total)	% children with $\geq 30\%$ improvement on ADHD-RS Total	27%	49.2%	27.3%	43%	27.2%	45.3%	24%
ADHD-RS Inattention subscale	% children with $\geq 30\%$ improvement on ADHD-RS Inattention subscale	27%	38.8%	28.9%	41.2%	28.2%	40.3%	26%
Clinical Global Impression-Improvement scale (CGI-I)	% children with score of $\leq 2$ (very much or much improved)	13.5%	25.4%	15.6%	28.8%	14.9%	27.6%	17%

A second month of treatment (Day 84) increased responder rates in ADHD symptoms and impairment.

Nearly 70% of parents reported improvement in ADHD-related impairment after using AKL-T01 for a second treatment month, in children on and off stimulant medication.

STARS-Adjunct open label trial responder rates in children on or off ADHD medication replicate response rates in STARS-ADHD RCT.

## Conclusions

A second AKL-T01 treatment month lead to increased responder rates in ADHD symptoms and impairment.

Comparable responder rates, across:

- ADHD medication status: children on versus off stimulants.
- Trial design: open label versus RCT.

## Methods

STARS-Adjunct was an open-label, 3-month trial, across 15 sites (NCT03649074).

Participants: 206 children, m/f, 8-14yo, with ADHD, `On stimulants` or not on any ADHD medication (`No Stimulants`) and ADHD-related impairment (IRS  $\geq 3$ ).

FIGURE 01 STUDY DESIGN

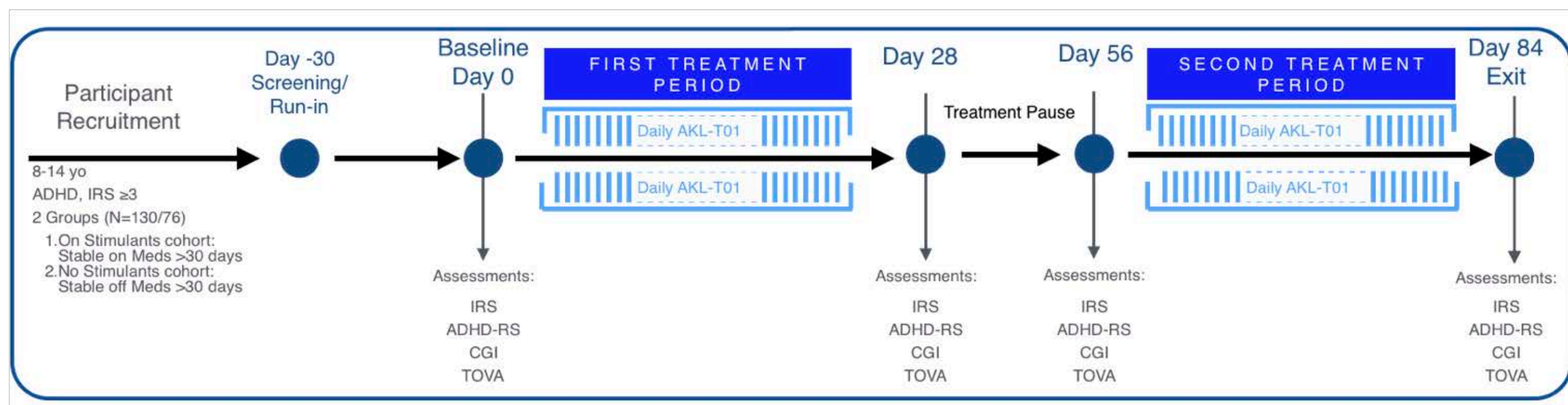


FIGURE 02 SCREENSHOT FROM AKL-T01



## REFERENCES

<sup>1</sup> 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.

## DISCLOSURES

ACC is on the advisory board and received research support from Akili interactive. SHK is consultant, received research support and may own stock or equity at Akili interactive. JL is employee at Akili interactive and may own stock options or equity at Akili interactive.