

# STARS-Adjunct: A Home-Based, Digital Treatment for Pediatric ADHD as Adjunct to Stimulant Medication: Insights on Repeat Administration and the Stability of Effects

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# Treatment with AKL-T01 showed similar improvements in ADHD-related symptoms and impairments in children with ADHD whether they were on stimulants or not on any ADHD medication. Improvements remained stable during a 4-week treatment pause, and further increased with a second 4-week AKL-T01 treatment.

## 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?

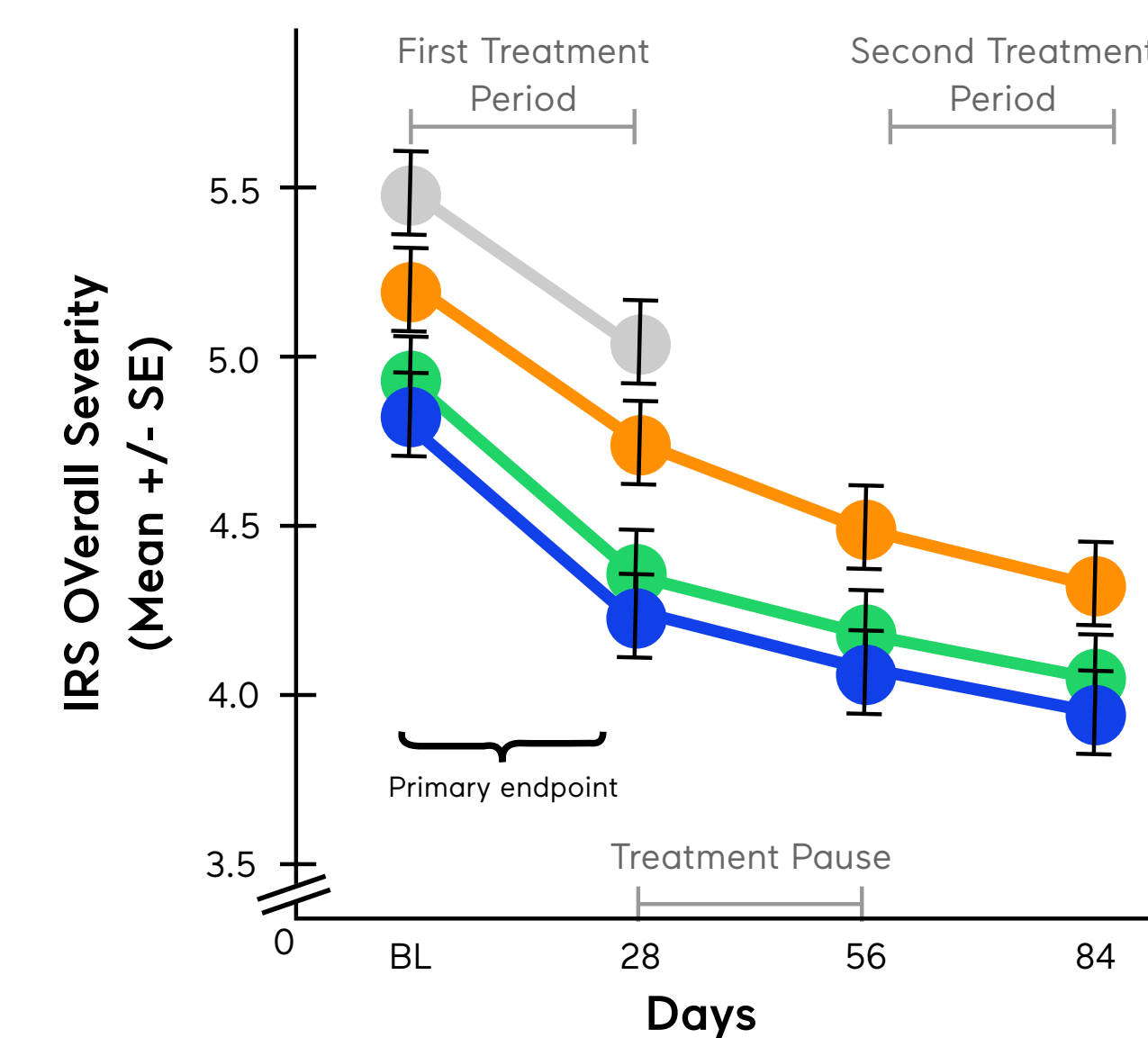
AKL-T01 is a digital treatment designed to improve attention function in ADHD delivered through a video-game interface.

A previous STARS-ADHD RCT found that AKL-T01 improved measures of objective attention, ADHD symptoms, and impairment in children without ADHD medication after 4-weeks (~ 25 minutes/day, 5 days/week, for 4-weeks).<sup>1</sup>

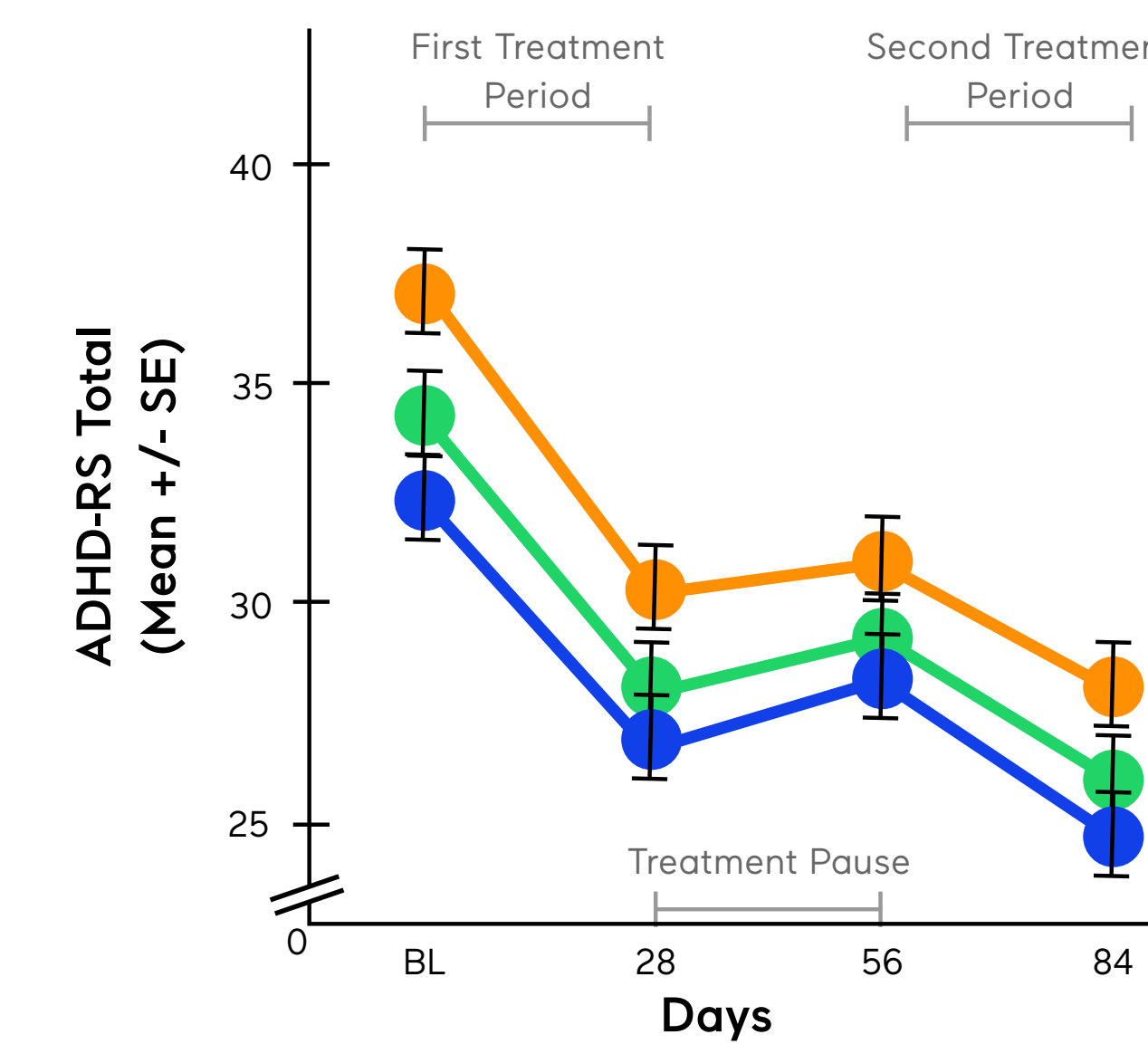
## Results

● STARS-Adjunct (No Stimulants) ● STARS-Adjunct (On Stimulants) ● STARS-Adjunct (Both Cohorts) ● STARS-ADHD RCT

### ADHD-related impairment (IRS) Improvement



### ADHD symptoms (ADHD-RS Total) Improvement



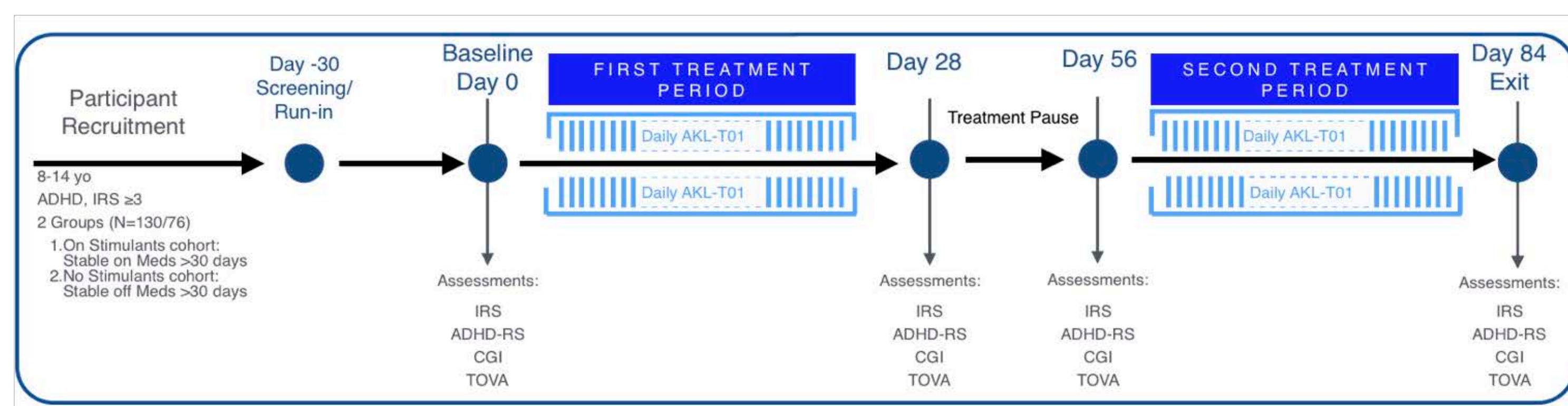
	STARS-Adjunct (On Stimulants)			STARS-Adjunct (No Stimulants)		
	Baseline Mean (SD) n	Change Mean (SD) n	Cohen's d t-statistic p-value	Baseline Mean (SD) n	Change Mean (SD) n	Cohen's d t-statistic p-value
ADHD-RS Total	32.7 (9.8) 130	-6.1 (7.18) 128	.85 -9.61 <0.001	37.0 (8.78) 76	-7.4 (9.92) 74	.74 -6.39 <0.001
IRS	4.8 (0.95) 130	-0.7 (1.04) 128	.65 -7.38 <0.001	5.1 (.88) 76	-0.5 (.89) 74	.59 -5.07 <0.001
CGI-I	-	3.3 (0.84) 128	.81 -9.14 <0.001	-	3.4 (0.83) 74	.70 -6.04 <0.001

## 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 ≥ 3 at Baseline).

FIGURE 01 STUDY DESIGN



### Demographics:

	On Stimulants	No Stimulants
Age Mean (SD)	10.6 (1.75)	10.5 (1.82)
Sex (Male)	98/130 (75.4%)	56/76 (73.7%)

FIGURE 02 SCREENSHOT FROM AKL-T01



## Safety

No serious device-related AE. 18% participants experienced an AE, with `decreased frustration tolerance` being the most common (13.1%). 3 AE-related dropouts.

## Conclusions

**Growing body of evidence for AKL-T01 as a digital therapeutic for attention in ADHD.**

**Comparable effects across:**

- ADHD medication status (children on versus off stimulants)
- Trial design (open label versus RCT)

### REFERENCES

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

SHK is consultant, received research support and may own stock or equity at Akili interactive, ACH and JL are employees at Akili interactive and may own stock or equity at Akili interactive.