Learnings from DTC early access release of a digital therapeutic for ADHD in response to the COVID-19 FDA policy for digital health devices for the treatment of psychiatric disorders

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BACKGROUND

- Treatment of attention deficit hyperactivity disorder (ADHD) includes pharmacological and non-pharmacological interventions, both of which have demonstrated efficacy.
- Digital therapeutics may offer improved access, minimal side effects, and low potential for abuse while providing targeted treatment options for improving cognitive functions, such as attention.

- Clinical trials, including the STARS-ADHD RCT, showed that AKL-T01 (now EndeavorRx®) improves objective attention in children 8-12 years old with ADHD and inattention.[1]
- In April 2020, FDA issued a COVID-19 emergency guidance to allow patients with psychiatric conditions access to low-risk, validated digital health devices.
- Objective: to describe real-world learning from early access to AKL-T01 in response to the FDA policy.

METHODS

From April to August 2020, 3-month access was provided to children:

- 8-12 years old (US only)
- parent-reported ADHD-diagnosis
- Parents agreed to contact their child's healthcare provider before using the product

Recommended use was:
Play 5 days/week, ~25 minutes (5 missions) a day, for at least 4 weeks.
Surveys were sent online at treatment start (Day 1) and after 1 month (D30), including:

- **Child cognitive functioning** (Patient Reported Outcomes Measurement Information System, PROMIS, parent-proxy, 8 selected items[2])
- **ADHD-related impairment** (Impairment Rating Scale, IRS, parent-report[3])

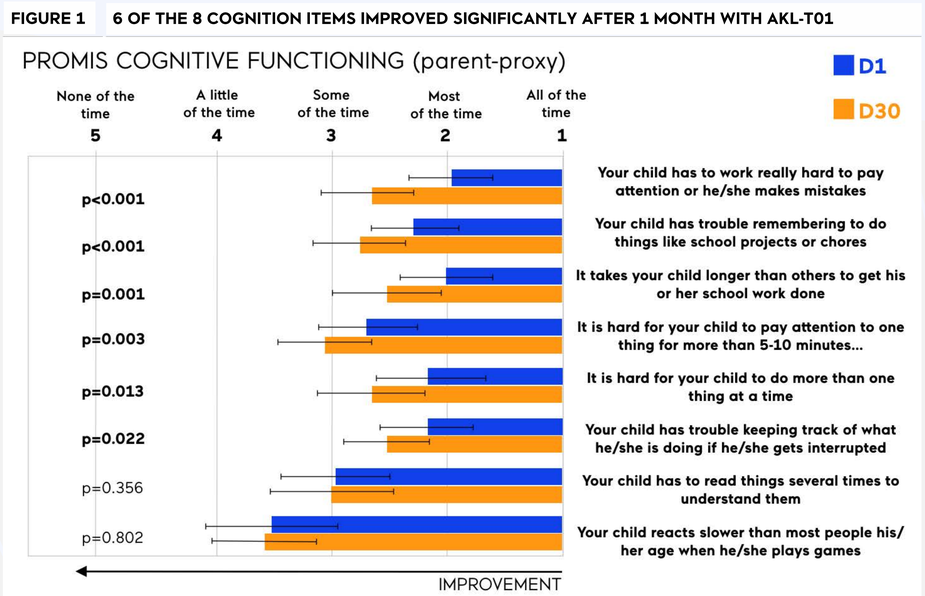
Pre-post comparisons for PROMIS items and the IRS were calculated (based on caregivers who filled in D1 and D30. Compliance was monitored throughout the access period.

RESULTS

- ✓ During this direct-to consumer early access release, AKL-T01 was activated 446 times, 419 children started the treatment and 357 children played at least one full AKL-T01 mission (80% male, average 10.3 years old, across 42 states).
- ✓ 111 caregivers answered the D1 survey and 68 the D30 survey. 29 caregivers answered both the Day 1 and D30 survey (partial or complete responses).
- ✓ Parents saw significant improvement in 6 of the 8 selected PROMIS cognitive functioning items.

Children played AKL-T01 across 42 states

FIGURE 1 **6 OF THE 8 COGNITION ITEMS IMPROVED SIGNIFICANTLY AFTER 1 MONTH WITH AKL-T01**



Further, ADHD-related overall impairment severity improved (IRS mean improvement=0.6, p=0.053). This improvement is comparable to the clinical RCT (STARS-ADHD RCT: IRS mean improvement: 0.55).

Compliance:
29% of children played at least half of the recommended use, compared to 86% in the previous STARS-ADHD RCT.
On days where children played they completed on average 4.34 missions (of 5 recommended)
Nearly 20% of users requested a reactivation after their first treatment month.

CONCLUSIONS

AKL-T01 **direct-to-consumers early access release was feasible**, but compliance was not as high as in the structured setting of previous clinical trials.

Caregivers observed **improvement** in their child's **cognitive functioning** and reduction in the ADHD-related **impairment** severity.

Caveats: open label, small sample, and non controlled.

Future studies should provide insights into AKL-T01's real-world compliance and efficacy as a prescription product.

REFERENCES

[1]Kollins et al., A Novel Digital Intervention for Actively Reducing Severity of Pediatric ADHD (STARS-ADHD): A Randomised Controlled Trial, The Lancet Digital Health 2, no. 4 (April 1, 2020): e168–78.

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[3] Fabiano, Gregory A., et al. "A practical measure of impairment: Psychometric properties of the impairment rating scale in samples of children with attention deficit hyperactivity disorder and two school-based samples." Journal of Clinical Child and Adolescent Psychology 35.3
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DISCLOSURES

LP, EC, LJ, AJ: are employed at Akili Interactive Labs and may own stock options