A MULTICENTER, RANDOMIZED, ACTIVE-CONTROL REGISTRATION TRIAL (STARS-ADHD) TO ASSESS THE EFFICACY AND SAFETY OF A NOVEL, HOME-BASED, DIGITAL TREATMENT FOR PEDIATRIC ADHD

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INTRODUCTION

• There are well-established pharmacologic and neurobehavioral therapies for attention-deficit/hyperactivity disorder (ADHD), but limitations in these treatments likely contribute to poor adherence over time. There is an ongoing need for novel approaches to improve adherence and address critical unmet needs in ADHD treatment.

• The study design was guided by the conceptual framework for behavior change that is critical for sustained improvement in the management of ADHD, including the importance of engaging neural networks involved in cognitive control.

• The primary outcome was symptom improvement in children with ADHD, as measured by the Attention Deficit Hyperactivity Score (ADHD-RS) total score.

METHODS

STUDY DESIGN AND PATIENTS

• SIMULATION (AKL-T01) was a multisite, randomized, double-blind, placebo-controlled registration trial conducted across 20 sites in the USA (Figure 1). (n=180, N=168, respectively) between May 26, 2016 and July 28, 2017. Patients were monitored and assessed for 12 weeks in the clinic and up to 12 additional weeks at home, with monthly/quarterly telephone follow-ups.

• The inclusion criteria included a diagnosis of ADHD according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). (n=180, N=168, respectively) was performed.

• The exclusion criteria included participation in another clinical trial within the last 90 days, current stimulant medication, and any contraindications to the study medication.

OUTCOMES

• The primary efficacy outcome was the effect of AKL-T01 versus active control on ADHD symptoms, measured using change in score of the ADHD-RS total score at post-intervention.

• The study also had a pre-specified secondary efficacy outcome that was defined by the Shapiro-Wilk test for normality and the Fuchs test for homogeneity of variances across treatment groups.

ANALYSES

• The statistical test for statistical significance for the primary endpoint was adjusted to 0.05 to account for multiplicity.

• Type I error was controlled by a step-up bootstrap method for secondary endpoints.

RESULTS

Efficacy

Primary and secondary outcomes based on the patients who discontinued stimulant medication and received AKL-T01 or active control are presented in Table 2. (N=180, N=168, respectively) for the AKL-T01 and active control groups, respectively; adjusted p=0.993; unadjusted p=0.617; Wilcoxon rank-sum test). (Figure 2)

• In post-hoc within-group analyses (Wilcoxon signed-rank test), significant improvements were observed with both AKL-T01 and active control (Table 2).

• In post-hoc within-group analyses (Wilcoxon signed-rank test), significant improvements were observed with both AKL-T01 and active control (Table 2).

CONCLUSIONS

• Results from this pivotal trial show that AKL-T01 improved inattention and inhibitory control as evidenced by a statistically significant improvement in the primary outcome, (t=0.0 A. V. A.) tests with active control.

• Although AKL-T01 also improved symptoms and functional outcomes, these improvements did not differ from those of the active control.

• The subgroup of patients that discontinued stimulant medication and received AKL-T01 showed improvements in ADHD symptoms (ADHD-RS-H and ADHD-RS-I), and clinical improvements (FOG), compared with the active control.

• AKL-T01 was well tolerated with a low incidence of AEs and high adherence with treatment.

• Further studies are needed to determine the effects of AKL-T01 in the broader ADHD population, including those with comorbid disorders and those receiving medication.

• Overall, results from this study suggest that AKL-T01 is an effective and novel digital treatment option for inattention and inhibitory control in children with ADHD that should be considered as part of an ADHD treatment program.

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REFERENCES


DISCLOSURES

• The authors report no financial interests in the development of the study, and no financial interests in the development of the medication.

• The manuscript has been reviewed and approved for publication by all authors.

• The authors have no conflicts of interest to declare.

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