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A randomized trial of cannabinoid treatment in children with autism spectrum disorder

An urgent need for novel pharmacological treatments for autism spectrum disorder (ASD) and the role of endocannabinoid dysfunction in animal models of ASD motivated this placebo-controlled, double-blind study. We evaluated two oral cannabinoid solutions: (1) a whole-plant cannabis extract containing cannabidiol (CBD) and Δ9-tetrahydrocannabinol (THC) in a 20:1 ratio and (2) purified CBD and THC in the same ratio. The study included 150 participants (ages 5–21) with ASD (ClinicalTrials.gov no. NCT02956226). Participants were randomized (1:1:1) to receive either placebo or one of the two cannabinoid treatments for 12 weeks, followed by a 4-week washout and crossover to alternate treatment for another 12 weeks.

The primary outcome measures assessed behavioral improvements (difference between whole-plant extract and placebo) using the Home Situation Questionnaire-ASD (HSQ-ASD) and the Clinical Global Impression-Improvement scale (CGI-I). Secondary measures included the Social Responsiveness Scale (SRS-2) and the Autism Parenting Stress Index (APSI).

Disruptive behavior on the CGI-I was rated as "much" or "very much" improved in 49% of participants receiving the whole-plant extract (n=45) compared to 21% on placebo (n=47; p=0.005). Median SRS Total Scores improved by 14.9 points with the whole-plant extract (n=34) versus 3.6 points with placebo (n=36; p=0.009). Changes in HSQ-ASD and APSI Total Scores did not significantly differ between groups. No treatment-related serious adverse events were reported. Common adverse events included somnolence and decreased appetite.

This interventional study provides evidence that CBD-rich cannabinoids, administered for three months, are well tolerated and may improve behavioral and social deficits in children with ASD.

Keywords: Autism spectrum disorder, cannabinoids, cannabidiol, tetrahydrocannabinol, Entourage effect

Biography

Dr. Aran's research and clinical work is focused on the diagnosis and treatment of autism spectrum disorder (ASD). As part of these efforts, Dr. Aran's group found substantially lower levels of circulating endocannabinoids in children with ASD, corroborating in humans, dysregulation of the endocannabinoid system in ASD. Dr. Aran also initiated the first studies exploring the effects of cannabidiol-rich cannabis in children with ASD including a placebo-controlled trial in 150 children with ASD, demonstrating the efficacy and tolerability of cannabinoids in ASD.

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