UC San Diego News Center

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Current Clinical Trial Assessing Potential of CBD in Treatment of Autism

UC San Diego researchers recruiting participants, ages 7 to 14, to determine whether cannabidiol, an extract of cannabis, can reduce behavioral symptoms of severe autism spectrum disorder

Researchers at University of California San Diego School of Medicine are recruiting eligible children between the ages of seven and fourteen years for a Phase III clinical trial to determine whether cannabidiol (CBD) reduces severe behavior problems in children with autism spectrum disorder (ASD).

CBD is a non-psychoactive compound found in the cannabis plant. It is widely marketed for diverse therapeutic benefits, from reducing chronic pain, acne and anxiety to treating cancer. In most cases, however, supporting empirical evidence is scant or non-existent.



Cannabidiol oil, an extract of the cannabis plant, is being tested as a possible therapeutic for reducing severe behavior problems in children with autism spectrum disorder. Photo credit: <u>Pixabay</u>

One exception is the use of CBD to treat two forms of severe epilepsy. In 2018, the U.S. Food and Drug Administration approved the use of Epidiolex, prescription solution of highly purified CBD developed by Boston-based Greenwich Biosciences, to treat seizures associated with Dravet syndrome and Lennox-Gastaut syndrome.

CBD has been found to modulate nerve cell messages in regions of the brain regulating anxiety, executive function and behavior, blocking signals to key neuronal receptors that, when overstimulated, may trigger seizures.

"Studies using animals modeling ASD have shown that CBD has similar effects: Excitatory neurotransmitters are inhibited, leading to a reduction of behavioral and social deficits characteristic of ASD," said Doris Trauner, MD, Distinguished Professor of Neurosciences and Pediatrics at UC San Diego School of Medicine and an attending pediatric neurologist at Rady

Children's Hospital-San Diego with special expertise in neurodevelopmental disabilities. "CBD may have potential for many neurological disabilities, but there is particular interest in autism because the behavioral problems can be severe and limit the child's ability to learn and socialize."

Trauner is principal investigator of the current clinical trial: a randomized, double-blind crossover study that seeks 30 participants, ages 7 to 14, with diagnosed cases of autism and severe symptoms. Children with epilepsy are excluded from the study. All participants will receive behavioral testing, MRI scans and electroencephalograms.

In the first phase of the study, half of the participants will receive CBD and the other half a placebo; both in the form of self-administered, flavored oral drops. In the second phase, after a period to allow participants' systems to "washout," the groups will be switched with the half that originally received CBD getting the placebo while the initial placebo group receives CBD. Investigators will be blinded to which participants are receiving which treatment until after testing is completed.

CBD does not produce the effects of feeling "high," which are caused by tetrahydrocannabinol or THC (the psychoactive ingredient in marijuana). But as one of more than 100 compounds called cannabinoids in cannabis, CBD interacts with the body's endocannabinoid system, a network of neurotransmitters that regulate diverse physiological and cognitive processes and response to stress.

ASD affects an estimated one in 68 children in the United States, primarily boys. The neurodevelopmental disorder is complex, with multiple known or suspected causative factors, from inherited genetic mutations to environmental conditions to metabolic dysfunction. A major consequence is abnormal development and functioning of connectivity and communications between brain cells and among neural networks, resulting in many of the observed social and cognitive impairments in persons with ASD.

The clinical trial is conducted in partnership with the Wholistic Research and Education Foundation and based at the <u>Center for Medicinal Cannabis Research</u> at UC San Diego School of Medicine.

For more information on the CBD-autism clinical trial, contact Lauren Smith at lmsmith@ucsd.edu or 619-627-1133.

Scott LaFee, 858-249-0456, slafee@ucsd.edu

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