

# UM to Study if CBD Combined with a Psychedelic Drug Can Treat Combined Traumatic Brain Injury and PTSD

University of Miami Miller School of Medicine researchers have received \$1.624 million in funding from Tassili Life Sciences, a company focused on psychedelic treatment research, to study whether using a pill form of cannabidiol (CBD) and the psychedelic drug psilocybin effectively treats and possibly prevents symptoms of two conditions that commonly occur together: mild traumatic brain injury (mTBI) and posttraumatic stress disorder (PTSD).



“Mild traumatic brain injury, especially concussion, is an important cause of morbidity in the United States and in the world today,” said study author Michael E. Hoffer, M.D., professor of otolaryngology and neurological surgery.

What many do not realize is that TBI often occurs along with posttraumatic stress disorder. Up to 40% of people impacted by

mTBI, a head injury causing a temporary change in mental status or consciousness, or TBI in general also suffer from PTSD. This combination of mTBI and PTSD is even more common in U.S military members, according to Dr. Hoffer.

“As a result, they’re disabled not just by the sequelae of the head injury, which can be dizziness, hearing disorders, memory issues, and headaches, but also posttraumatic stress symptoms that complicate the disability after the head injury,” Dr. Hoffer said.

Other than medicines that can mask individual symptoms related to the conditions, there are no proven pharmacological treatments or curative options for TBI alone, or TBI and PTSD combined.

“With this new grant with Tassili, we have the opportunity to explore a combination therapy that might treat the traumatic brain injury as well as the PTSD,” Dr. Hoffer said.

### **A combination pill for a combination disorder**

Dr. Hoffer and colleagues have for years studied CBD’s effect on TBI.

“CBD has the potential to treat the sequelae of traumatic brain injury, including hearing loss, balance disorders, memory and other cognitive issues. It has the ability to treat these disorders and “prevent them from becoming significant issues after the concussion,” Dr. Hoffer said.

Researchers from not only the Miller School but also Johns Hopkins, Yale and the University of Wisconsin are conducting research looking at psychedelics for the treatment of

different brain conditions. In this case, Dr. Hoffer and colleagues are studying psilocybin because the psychedelic drug has properties known to impact PTSD.

“Our goal is to develop a prescription pill with these ingredients that treat mTBI and PTSD,” he said. “This is a new and increasingly exciting area. Adding this project to the school’s portfolio allows us at the University of Miami to stay on the cutting edge of modern research.”

### **Off and running**

Basic lab research for the Tassili-funded study began this month. Researchers are using an animal model to examine the effects of both medicines given orally on the sequelae of mTBI and PTSD.

“We hope to complete the proof-of-concept basic animal studies in the next 9 to 12 months and then move on to a parallel investigation to determine optimal dosing and timing. Then, we plan to move to a human study, hopefully filing with the FDA early in 2021,” Dr. Hoffer said.

The U.S. Departments of Defense (DoD) and Veterans Affairs (VA) are among the organizations eager to find safe and effective treatments for TBI and PTSD. The tricky part about doing research on drugs like psychedelics and CBD is traditional government programs don’t fund the research until early studies prove their safety and efficacy.

“We credit Tassili for having the forethought because this research is difficult. While it is recognized and respected, federal institutions are not going to give you support for

this until you have shown that you have something,” Dr. Hoffer said. “We will be able to compete for VA, NIH and DoD grants with the data we get from this work. But someone had to step in and get us going on it, so we can develop the pilot data needed to compete for federal funds.”

Toronto-based Tassili Life Sciences collaborates with university research institutes to study clinical and physiological effectiveness in post-concussion syndrome, PTSD and obsessive-compulsive disorder (OCD) with timely, measured doses of psilocybin and CBD. The company expects the combination will lead to clinical outcomes that are superior to psilocybin or CBD alone, according to TassiliLifeSciences.com.

Tassili CEO Jonathan Gilbert has worked with the University of Miami and Dr. Hoffer on previous research on CBD for concussion.

“After having such a positive and successful experience with Dr. Hoffer and the University of Miami, I knew there was no better place with whom to sign an agreement. This time, I’m embarking on a project focused on psilocybin and the effects of psychedelics, as it could potentially be efficacious for PTSD,” Gilbert said. “This is a fantastic team to study the effects of psychedelics, particularly psilocybin, in treatment of PTSD.”

This study is a collaborative effort across four Miller School departments: neurology, The Miami Project to Cure Paralysis, otolaryngology and biomedical engineering. Study authors include: W. Dalton Dietrich, Ph.D., professor of neurological surgery, neurology and cell biology, and scientific director

at The Miami Project to Cure Paralysis; Helen M. Bramlett, Ph.D., professor of neurological surgery; Bonnie Levin, Ph.D., director of neuropsychology and professor of neurology; Suhrud Rajguru, Ph.D., associate professor of biomedical engineering and otolaryngology; and Gillian Hotz, Ph.D., director of the UHealth Concussion Program.