Researchers studying MDMA-assisted treatment for PTSD

June 18 2024, by Jeremy Redmon, The Atlanta Journal-Constitution

Credit: Unsplash/CC0 Public Domain

Therapists have discovered a variety of effective treatments for patients with post-traumatic stress disorder: Talk therapy, narrative writing, medication and a system that involves discussing painful experiences while focusing on blinking lights and vibrations.

But not everything works for everyone living with PTSD, a serious mental health problem that affects 5% of adults in the United States, many of them military veterans, according to the U.S. Department of Veterans Affairs.

Now researchers at the Emory Brain Health Center are studying how MDMA—a psychedelic drug commonly known as ecstasy—could help PTSD patients when combined with a proven form of psychotherapy called prolonged exposure treatment.

"We need treatment options," said Barbara Rothbaum, a clinical psychologist at Emory and one of the study's investigators. "People are able to approach distressing memories with less distress when they are on MDMA—with less anxiety."

The research at Emory comes as the U.S. Food and Drug Administration weighs an application for MDMA-assisted therapy. That application was submitted by Lykos Therapeutics, a corporation created by the psychedelic studies association.

An FDA advisory committee concluded the available data do not show MDMA is effective for patients with PTSD and that the benefits of such treatment would not outweigh the risks to patients. The FDA, which is not bound by the advisory panel's recommendations, is expected to make a decision by Aug. 11.

Military veterans and women are more likely to develop PTSD, which can be caused by life-threatening events, such as combat, and sexual trauma, according to the VA's National Center for PTSD, which says about 13 million Americans had PTSD in 2020.

Symptoms can include nightmares, flashbacks, hypervigilance and difficulty concentrating and sleeping. Patients might avoid situations or

people that remind them of their traumatic experiences. Meanwhile, according to the VA, studies show the risk of suicide is higher for people with PTSD.

In searching for other ways to treat patients with mental health problems, researchers have turned to psychedelics. For example, experts at Emory and across the nation are learning in clinical trials that drugs derived from fungi—sometimes called magic mushrooms—can help people experiencing PTSD, pain and addiction.

MDMA, a synthetic drug also called midomafetamine, can cause hallucinogenic and stimulant effects. It is listed as a Schedule I substance in the United States, meaning it has no accepted medical uses and is known to have a high potential for abuse, according to the U.S. Drug Enforcement Administration.

Lykos submitted to the FDA data from four 18-week studies of how MDMA—combined with psychotherapy—works to help PTSD patients. The results showed participants appeared to experience "rapid, clinically meaningful, durable improvements in their PTSD symptoms," according to an FDA report.

Because MDMA can profoundly alter mood, sensation and suggestibility, most of Lykos' trial participants were able to accurately guess whether they were given the drug or a placebo, according to the FDA report. That could have introduced what the FDA report called "expectation bias" in which participants who believed they received MDMA expected they would get better, while those who believed they received a placebo fared worse because of disappointment.

A nonprofit research group called the Institute for Clinical and Economic Review underscored concerns about bias in a report it released last month, adding "the publicly available evidence is

insufficient to assess the balance of benefits and harms."

Nese Devenot, a senior lecturer at Johns Hopkins University, joined more than 70 fellow college educators, researchers and others in submitting a petition to the FDA, citing ICER's report and asking for an extended public hearing.

"The FDA must take action to ensure that this does not amount to another regulatory scandal like the opioid crisis, where widespread harm retroactively illuminated substantial regulatory failures," the petition says.

Before it voted, the FDA's advisory panel heard from many proponents, including some of Lykos' study trial participants. Among them was Cristina Pearse, a Colorado resident who leads a nonprofit organization focused on helping women recover from trauma. Pearse told the panel she was sexually assaulted as a young child and was diagnosed with PTSD when she was 45.

"I nearly died from PTSD—this trial saved my life," she told The Atlanta Journal-Constitution. "All of my work now underscores the fact that I believe this therapy works. The FDA advisory committee is wrong. We need it now for those whose life also hangs in the balance. It will save lives."

Lori Tipton, a writer and public speaker based in New Orleans, told the panel she participated in one of Lykos' studies after living with PTSD for more than a decade. She lost her brother to an overdose in 1999 and said her mother killed two women and herself in 2005. Tipton added that her life was filled with anxiety and hypervigilance.

"I no longer endure the symptoms that tormented me for years, experiencing a newfound ease in laughter and a profound sense of

lightness, calmness and reduced agitation," she said. "What's most significant to me is the presence it has granted me, enhancing my enjoyment of motherhood. I am deeply thankful to MDMA-assisted therapy for reshaping and enriching my bond with my child."

The committee also heard from patients who said they had troubling experiences with MDMA-assisted treatment. One man warned about what could happen with inept or inexperienced therapists. Without naming his therapist or saying whether he was part of a study, he said the treatment he underwent last year "completely derailed my life," adding he now experiences extreme exhaustion and severe cognitive impairment.

"I have been unable to work for the last 15 months," he told the panel. "And I have had to live with a family member while I attempt to recover on my own."

Rothbaum, who also leads the Emory Healthcare Veterans Program, emphasized her university's study was approved by the FDA and the DEA and that its patients are being screened for safety.

She also underscored that Emory's study is shorter and different than what Lykos is proposing. Patients at Emory, for example, receive only one MDMA dose during 10 days of psychotherapy treatment followed by assessments. Lykos is proposing three medication sessions with MDMA during a four-month treatment.

Two patients—both military veterans—have completed MDMA-assisted therapy as part of Emory's study. A third patient is enrolling. The researchers plan to study at least a dozen more, including civilians, and hope to report results by next year.

"We have been able to do the treatment as we planned," said Jessica

Maples-Keller, a clinical psychologist and one of the Emory study's investigators. "And the initial results are very promising."