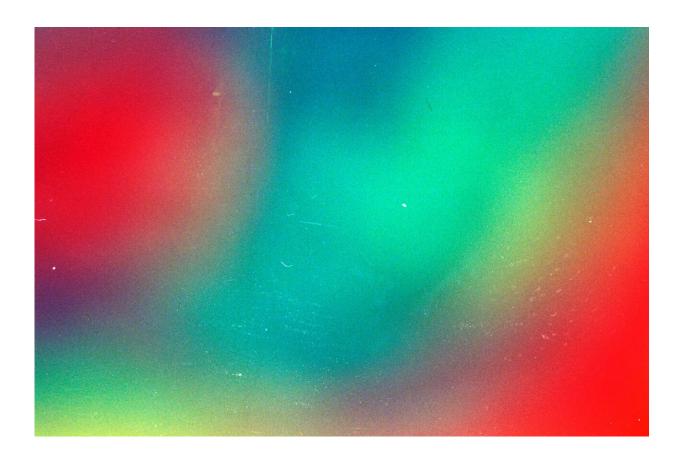


Florida researchers are giving depressed, anxious people psychedelics

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A therapy session with Patricia Brown starts like any other. She leads her clients into a peaceful, quiet room, draped in beige and generic, calming artwork.



Then her clients lie down, close their eyes, put on a blindfold and headphones, and trip for six hours on psilocybin, the psychoactive chemical found in magic mushrooms.

Brown is a psychiatric nurse practitioner and head of clinical operations at CNS Health care. CNS in Thornton Park and APG Research near the Central Business District are two global clinical trial sites testing whether microdoses of psychedelics—typically about one-tenth of a recreational dose—can help people with depression and anxiety.

A growing number of clinical trials suggest single doses of psychedelics can have long-lasting impacts on the brain, leading the U.S. Food and Drug Administration to issue "breakthrough therapy" designations to these drugs beginning in 2017.

These treatments could have untapped potential for helping the estimated one in three people with <u>treatment-resistant depression</u>, meaning they have tried at least two different antidepressants that haven't worked, said Brown. The clinical trial she's working on right now targets this group.

"This is the opportunity for us to take treatment for depression and anxiety to the next level," Brown said.

The rebound in psychedelics' popularity isn't without controversy, however. A potentially troubling trend is emerging. From 2018 to 2021, a <u>survey published</u> in the scientific journal *Addiction* indicates a doubling of recreational <u>psychedelic</u> use in the U.S., with 8% of young adults having tried hallucinogens as of 2021. This is the highest number seen since the 1980s.

Recreational use sparks concern



This isn't the first time these drugs have been studied for therapeutic benefits. These investigations have taken place since the 1940s, though research halted in the 1970s when the <u>federal government</u> classified these drugs as Schedule 1 due to their potential for abuse.

Over the last few decades, there's been a resurgence in promising scientific research, continuing the work of 50 years ago. But it's dangerous to use these drugs outside a medical setting, especially without a guide, said Dr. Robert Molpus, a psychiatrist and addiction researcher.

Molpus leads the CNS Health care location of a <u>clinical trial</u> of small doses of LSD on people with anxiety. The study is run by Mind Medicine, a biotech pharmaceutical company seeking approval for its proprietary form of LSD.

"What we have here is pharmaceutical-grade medication produced under very strict tolerances and standards," said Molpus. "Whatever you buy on the street, it's not pharmaceutical grade and you actually have no idea what's in it or what the dose is."

Psychedelics theoretically alleviate <u>mental illnesses</u> by creating new connections in the brain, according to the National Institutes of Health. Negative connections can be created just as easily as positive ones, Molpus warned.

"The idea is that things are connected wrong because of experience or trauma. And so, what you want to do, is get them reconnected; you want to break this bad connection," Molpus said. "You don't want a different set of bad connections. That's where the therapy piece comes in."

Licensed mental health counselor Elizabeth Lindell Mendez says recreational psychedelics worsened pre-existing mental illnesses and addiction issues in some of her clients. She worked for six years in



community mental health residential and day treatment programs before moving to Thriveworks Counseling & Psychiatry in Maitland a few months ago.

"When you actively hallucinate, the more you do it, the less likely you might be to come back, especially if you have a hereditary predisposition that you're unaware of," she said. "It can actually increase and exacerbate symptoms."

She emphasized that she hasn't seen any clients who took these drugs within a controlled medical setting.

The American Psychological Association released a statement in 2022 calling preliminary research into psychedelics "promising" but cautioned about a lack of evidence.

"There is currently inadequate scientific evidence for endorsing the use of psychedelics to treat any psychiatric disorder except within the context of approved investigational studies," the statement read.

Studies combat stigma

Brown is confident that current clinical trials are not dangerous.

"I think there really is a stigma that we have to overcome," she said.

The ongoing trials at CNS are regulated by the FDA and don't allow people with psychotic and personality disorders to participate. People with other mental illnesses like <u>post-traumatic stress disorder</u> and people who would take other psychiatric medications during the study can't participate either.

Brown is working on a randomized clinical trial testing the impact of a



single dose of psilocybin. The study, conducted by biotech company COMPASS Pathways, will include therapy before the psilocybin dose, a therapist present for the eight-hour period a patient is high, and additional therapy afterward to process what the participant has experienced and help them integrate what they've learned.

Another point to keep in mind is that psychedelics do not typically lead to addiction, said Molpus.

"Can you overuse it? Absolutely, you can. But it's actually not all that common," Molpus said. "It can happen, and it does happen, but it's not like meth or heroin that can really capture and trap people in addiction."

Decades of research back up that assertion, <u>according to the National Institutes of Health.</u>

A push to roll back restrictions

The FDA labels psychedelics like psilocybin, LSD, peyote and MDMA (ecstasy) as having "high abuse potential" and no recognized medical use, hence their Schedule 1 classification.

This designation is theoretically reserved for the most dangerous and addictive drugs in the U.S. In recent years, advocates have questioned it. Molpus labeled psychedelics' classification "more political than medical."

Marijuana, too, is Schedule 1, despite decades of evidence of its potential therapeutic benefits. The majority of states, including Florida, have legalized it for medical use.

Amid mounting arguments that these drugs should be more accessible, a handful of countries and U.S. locations like Oregon have decriminalized



or legalized MDMA and mushrooms.

In 2021 and 2022, Florida lawmakers introduced legislation that would have ordered state-funded research into the therapeutic applications of psilocybin, ketamine and MDMA for treating conditions including depression, bipolar disorder, post-traumatic stress disorder, chronic pain and migraines. The bills failed to achieve widespread support.

Nationally, more than 60% of U.S. voters support legalizing psychedelic therapy, a 2023 poll done by the University of California, Berkeley, found.

The future of psychedelics

A potential roadmap for <u>magic mushrooms</u> and LSD can be seen with ketamine, another drug with hallucinogenic or psychoactive properties.

The FDA approved a derivative of ketamine called esketamine—manufactured by Janssen Pharmaceuticals and sold as a patented nasal spray called Spravato—in 2018.

It's only available for people with treatment-resistant depression through a restricted distribution system with strict guidelines.

Ketamine differs from traditional psychedelics, however, because it has been used in medical settings for decades and is not as tightly regulated. Physicians who don't want to jump through federal government hurdles or work with insurance companies are allowed to prescribe traditional ketamine off-label as a treatment for mental health conditions.

Meanwhile, the only foray into selling mushrooms commercially in Florida so far was unsuccessful.



In 2022, Ybor City's Chillum Mushroom Hemp Dispensary briefly bypassed Florida's restrictions by selling psychedelic mushrooms that didn't contain the banned ingredient of psilocybin. It advertised itself as the first magic mushroom dispensary in the U.S., and was so successful it opened a second St. Petersburg location.

Even though the mushrooms technically didn't include any banned ingredients, they were not approved to be sold as food. The store tried out a loophole, labeling them as intended "only for education or spiritual purposes," not for consumption.

This wasn't enough to stop the Florida Department of Agriculture and Consumer Services from shutting down Chillum Mushroom Hemp Dispensary's sales.

The dispensary reluctantly stopped offering the mushroom in August, according to a statement on its website.

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