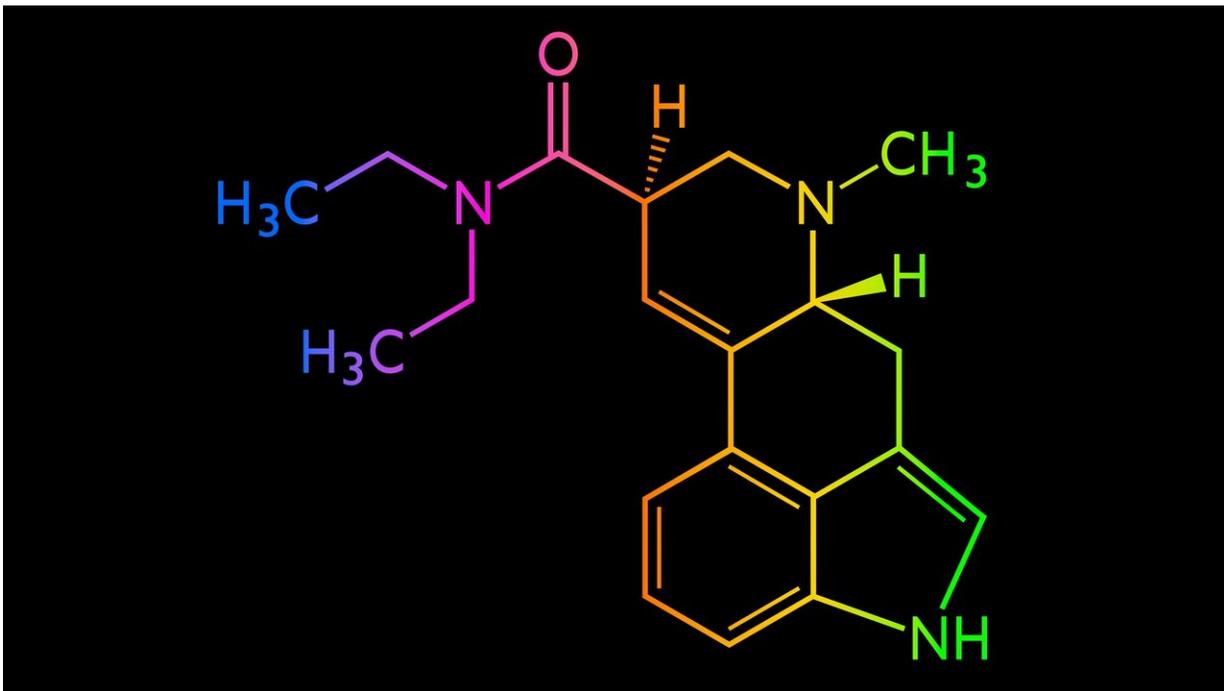


Miami clinic kicks off first national study of LSD, once a 'public enemy,' to treat anxiety

September 23 2022, by Natalia Galicza



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The gurus of the psychedelic era of American pop culture extolled the experience of the "acid trip." But the U.S. government and much of the public remained leery of LSD, with President Richard Nixon declaring it and assorted other drugs "public enemy No. 1."

Now, half a century after Nixon launched the War on Drugs, a Miami-

area private research clinic has kicked off a federally approved clinical trial to test LSD as a possible treatment for generalized anxiety disorder.

The milestone trial—billed by the drug developer as the largest study of LSD for potential commercial use ever conducted in the United States—reflects a growing body of research that suggests those hippies were maybe on to something: That the mind-altering power of LSD, mushrooms and a host of other hallucinogens—if administered in controlled amounts under [medical supervision](#)—might have some beneficial properties, particularly in treating psychological problems.

The inaugural dose of the latest trial was administered to a patient on Aug. 24 by Segal Trials, at its Center for Psychedelic and Cannabis Research in Miami Lakes.

The proprietary "pharmaceutically optimized" form of LSD is named MM-120 and owned by MindMed, a small psychedelic biotechnology company based in New York. MindMed's study could be a significant step in the long process of potentially bringing a new treatment for generalized anxiety disorder to the market. The study spans 20 clinics nationwide, including Segal Trials.

Rishi Kakar, medical director and chief scientific officer at Segal, said Miami-Dade's large population and diverse demographic make the county a perfect site for the medical trial.

"There are more patients here who have anxiety and don't have enough access to treatment, or the treatment is not meeting their goals," he said. "We as a geography are uniquely positioned for that in Miami. We have a breadth of diverse patient populations."

The study, kicking off a second phase, is designed to monitor both the drug's effects and to find the most effective dosage. Patients will receive

one of four different dose strengths while others will get a placebo. Segal Trials will likely contribute 10 to 20 patients out of the 200 MindMed is testing in this second phase.

Patients who receive doses will be monitored in a room designed to feel more like home than a sterilized clinic. The first patient in Miami Lakes, Kakar said, reclined on a couch while under the influence of the drug—headset, eye mask and blanket provided. Two guides with experience overseeing psychedelic-assisted psychotherapy monitored the patient for the entire duration of its psychoactive effects, which Kakar estimated to be about 12 hours.

Psychedelics—like LSD or "acid", Psilocybin or "magic mushrooms," among others—are not new, not in a recreational nor a therapeutic context. The psychoactive drugs were widely studied and administered to curb alcohol addiction, post-traumatic stress disorder, anxiety and depression in the United States until they became criminalized in 1968. Now, after steadily increasing community demand, they're reentering psychiatric research in a big way.

The past decade has been fruitful for research. Promising studies on Psilocybin as a treatment for anxiety, depression and addiction have multiplied alongside research into MDMA (Methylenedioxymethamphetamine)—"club drugs" more commonly called ecstasy or molly—as a potential treatment for post-traumatic stress disorder and addiction.

LSD was also widely studied, though mostly before the 1968 ban. The National Institutes of Health funded more than a hundred grants for the drug's study prior to its prohibition. Some of those studies also found use for the compound in quelling anxiety and addiction. Bill Wilson, founder of Alcoholics Anonymous, famously credits LSD for helping him on his road to sobriety.

Those studies and breakthroughs ran largely dry following the ban. But studies like MindMed's are sparking renewed interest in LSD, and a broad umbrella of possible psychedelic treatments.

Joseph Lichter, a chemist who teaches a "Psychedelic Renaissance" course at Florida International University's honors college, believes that such research could prove promising for the future of American psychiatry. The mind-altering substances have been feared or considered dangerous for decades, but are powerful non-toxic compounds that have captivated scientists and researchers since long before they were outlawed.

"We definitely need to see more science before we start putting these things into healthcare professionals' hands to use with clients, but it's really a good thing for us to work toward destigmatizing LSD," Lichter said. He believes there's no better place to kick start a psychedelic renaissance—a resurgence of research on the taboo substances—than Miami-Dade County.

"Anytime something is happening here in Miami-Dade County, I'm excited by it because we're a big metropolis," Lichter said. "I think the psychedelic renaissance right now is in a research-heavy period, and things like the trials at Segal are the correct steps forward."

Clinics offering Ketamine, a psychoactive sedative, already exist across the county. Psilocybin has also gained medical traction; Segal Trials conducted its own trials of Psilocybin-assisted psychotherapy for treatment of depression at its Miami Lakes center last summer.

"There is such a renewed interest, there is such a large unmet need in our community in that particular area," Kakar said. "And psychedelics look like they are getting more normalized in the minds of patients and communities versus being on the fringes of recreational use."

What sets MM-120 and other psychedelic treatments apart from more traditionally prescribed treatments for anxiety and depression is the length of effect. Rather than daily use, the drug candidate is being studied as a one-time treatment that promises—at least potentially—lasting benefits.

"Unlike current medications that have to be taken on a daily basis for a very long time and hopefully have a realized effect many weeks down the line, we believe if this medication is taken once under structured conditions, it can have a potential effect on anxiety that lasts for a very long time," Kakar said. "So we believe it works in a very different way pharmacologically than any other drug that has to be taken on a daily basis."

Robert Barrow, CEO of MindMed, has touted the potential in company press releases, pointing to one recent research paper from a partner in the MM-120 study.

MindMed, he wrote, is working with the University Hospital of Basel, Switzerland, which is the world's top research center for LSD in medical applications. Earlier this month, the University Hospital of Basel published a paper with results from its own study on how well LSD curbs anxiety.

"This paper further reinforces the positive preliminary evidence for LSD in patients who suffer from anxiety disorders," Barrow said. "Acute administration of LSD produced long-lasting and notable reductions of anxiety and co-morbid depression symptoms for up to 16 weeks. These results are encouraging."

It's unclear how long the second phase of the trial will last. Once there is enough data across all participating sites, MindMed will approve a specific dose of MM-120 to be studied in phase three. The third and

final phase will test a larger pool of patients with only the approved dose. It will be the last step before MindMed can submit the drug to the Food and Drug Administration for approval and possible future prescription usage. The company estimates the entire process will be complete by November of next year, but that could be subject to change if the phases drag on longer than expected.

But despite the promising research, LSD still arguably gets the worst rap out of all the [psychedelics](#). The drug has a tarnished reputation for being associated with counterculture, anti-war protests and "bad trips." It's powerful even in small amounts and, when taken in too high a dose or in an unstructured environment, can cause extreme stress or unsafe conditions for the user.

The stigma attached to LSD is why Lichter teaches his students a phrase coined by Humphrey Osmond, a British psychiatrist who coined the word psychedelic.

"'To fathom hell or go angelic, just take a pinch of psychedelic' is the phrase Osmond came up with," Lichter said. "There's a risk of going into a hellish place with this compound or a potential to go into an angelic place. We all have to have that recognition that there is a huge risk."

But, he said, there is a lot of room in between those extremes and the potential benefits are too enticing for some scientists not to support.

"In reality it's just a chemical compound that binds to a serotonin receptor and causes changes to the way people think or feel," Lichter said. "And if that change can actually help them, which is what some of these studies are showing, we need to destigmatize it and give it hope, give it the attention it deserves."

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