

Israel's Health Ministry approves compassionate use of MDMA to treat PTSD

Recreational use of MDMA, also known as ecstasy, is forbidden in Israel where the drug is considered dangerous. But a trial treatment may soon change that

Ido Efrati | Feb. 10, 2019 | 12:42 PM

MDMA, popularly known as ecstasy, is a drug more commonly associated with raves and nightclubs than a therapist's office.

Emerging research has shown promising results in using this "party drug" to treat patients suffering from post-traumatic stress disorder, and Israel's Health Ministry has just approved the use of MDMA to treat dozens of patients.

MDMA is classified in Israel as a "dangerous drug", recreational use is illegal, and therapeutic use of MDMA has yet to be formally approved and is still in clinical trials.

However, this treatment is deemed as "compassionate use," which allows drugs that are still in development to be made available to patients outside of a clinical trial due to the lack of effective alternatives.

By flooding the central nervous system with serotonin, MDMA produces strong feelings of euphoria, which can last over eight hours. It is considered a popular party drug because it keeps revelers awake and energetic.

MDMA will be administered to about 50 patients in the approved program who have been diagnosed with post-traumatic stress disorder in the course of psychiatric treatment.

In three out of 15 planned sessions, patients will be administered MDMA by specially trained staff at one of four hospitals around the country: Rambam Medical Center in Haifa and psychiatric hospitals in Be'er Yaakov, Lev Hasharon and Be'er Sheva.

The decision to proceed with the program follows extensive investigative work by the Health Ministry, which sent a representative for training in the United States who worked on a confidential basis through the California-based Multidisciplinary Association for Psychedelic Studies (MAPS).

It's possible that the Israeli Health Ministry could be two years ahead of global recognition of the treatment.

If matters proceed as planned, in 2021, the U.S. Food and Drug Administration will officially approve the treatment after deeming it a "breakthrough" therapy in 2017, a designation that puts it on a fast track to final approval.

The FDA's vote of confidence in the drug is a major milestone in the transformation of the use of MDMA from the margins to the heart of the medical establishment.

In February, about 50 caregivers convened at a hotel in Neve Shalom between Tel Aviv and Jerusalem for training on administering the drug, training that included role playing. "We are preparing the ground," said Dr. Keren Sarfati, the representative of MAPS in Israel who has been leading research on the use of MDMA in Israel, which is entering its third stage.

The decision to begin the initial use of the drug with the 50 patients is independent of the third stage clinical trials and is based on the positive results of the second stage.

"If we see positive results in the third stage and the FDA in fact approves the treatment in another two years, we want to have treatment centers and caregivers ready so we can start immediately. It's so urgent because of the major suffering that post-trauma victims experience – suffering that can also lead to suicide – and at the moment, they have no remedy."

The selection of the initial participants in the group of 50 is only expected to begin in about six months, and it can be assumed that there will be a rash of requests since hundreds of PTSD sufferers have asked to participate. Sarfati said the program is looking for patients with the most serious cases and who have not seen improvement from traditional treatments.

Patients will only be permitted to take the drug under constant supervision.

The treatment includes 15 psychotherapy sessions with two therapists, a man and a woman. In most instances, one of the two will be a psychiatrist, psychologist or clinical social worker. The patients will be asked to lie on a bed with the caregivers next to them. For a portion of the time, the patients will listen to music through earphones.

"The caregivers are always a man and a woman. It's mandatory," said Bella Ben-Gershon, who is in charge of treatment of mental trauma at the Health Ministry's mental health services division. "There is therapeutic rationale behind this, related to certain things that surface in treatment and in projections that the patient may make," she said, referring to a psychological phenomenon where patients externalize characteristics they dislike in themselves and attribute them to others. "These things require both a male and female presence."

Ben-Gershon returned from the United States about three weeks ago, where she personally underwent MDMA therapy. “It was a very significant, even critical experience,” she recalled. “It’s not fun and it’s no party. You work through serious matters. The substance enables you to return to those same experiences that were encapsulated and to reprocess them over a short period time. At the session itself, things sometimes happen very quickly and powerfully, and the results remain over time. That provides grounds for optimism.”

The Health Ministry became aware of the use of MDMA therapy as a result of Israel’s participation in the clinical trial, Ben-Gershon said. “The ministry is taking this seriously and with appropriate caution, and in-depth investigation has been carried out. There is a considerable population in Israel of people suffering from PTSD that is resistant to other treatment.”

The success rate of using MDMA to treat PTSD so far has been high, she said. “More than 2,000 patients around the world have undergone this treatment in studies, and we’ve seen that it does not involve a risk of worsening the patient’s condition or of side effects. The findings range from very successful results in the best cases and ineffectiveness in the worst, but they don’t indicate a chance of making the situation worse or causing harm.”

Before the treatments begin in Israel, all of the caregivers are due to undergo a session in which they take MDMA. One of the caregivers, Prof. Rachel Yehuda, is a psychiatrist and psychotherapist specializing in trauma at the Mt. Sinai Medical Center in New York. She has been studying the biological aspects of trauma for three decades.

Prof. Yehuda has been conducting research to classify various groups of patients and to predict their reactions to a range of treatments, including MDMA treatment, using blood tests. She is familiar with the entire spectrum of available treatments for PTSD and says they are not always successful.

She admitted that she was skeptical about the use of MDMA at first. Initially, she said, she thought the positive results only related to a small group, but the more she delved into the matter, the more she realized that it should be pursued further. The use of MDMA provides a link between the patient’s biology and personal history – giving access to the root of the trauma in a way that cannot be achieved through psychotherapy alone, she explained.

Hundreds waiting for treatment

Beyond the group of 50 patients that will undergo treatment, third-stage clinical trials are set to begin. In the trials, MDMA will be administered to hundreds of PTSD patients at 16 medical centers worldwide, including in Israel.

The Israeli study, which will take place at Sheba Medical Center at Tel Hashomer and the psychiatric hospital in Be’er Yaakov, will involve 14 patients. However, there is a waiting list of 600 people suffering from PTSD – from a range of traumas including military combat, abuse, sexual assault, and traffic accidents – who are eager to take part in this medical trial, which is the second of its kind in Israel.

The previous trial, which was conducted at the Be’er Yaakov hospital, involved ten patients in Israel as part of a global trial involving 107 people. The results were promising and were the basis for declaring MDMA a “breakthrough treatment.” A year after the trials, 68 percent of patients experience a dramatic decrease in symptoms, and some were completely asymptomatic.

The new trial is being led by Dr. Revital Amiaz, a psychiatrist who directs the ambulatory services at the psychiatric department at the Sheba Medical Center. Amiaz previously conducted a study on the use of ketamine for treatment-resistant depression. She believes that MDMA has treatment potential for PTSD sufferers. What convinced her in part was her personal experience, having been administered MDMA in the United States as part of a study of caregivers.

When she first arrived at her treatment session, she says she was frightened. However, she continued, “You feel as if barriers have been removed, as if there are things that were not linked in your mind, and all of a sudden, they were organized and the story comes together. It’s not a magical drug, but it makes the structure of the brain more elastic – which is inflexible among PTSD patients, and at the same time, it enables good communication. It provides tools to look more deeply into the psyche.”

Back at Neve Shalom

Back at the hotel in Neve Shalom, where the caregivers are trained, the executive director and founder of MAPS, Dr. Rick Doblin, was standing on the lawn with a smile on his face, and for good reason. His life’s work is beginning to bear fruit.

Doblin, whose doctorate dealt with the regulation of medical marijuana and psychedelic substances in the United States, has made a major effort to raise funds for medical research on psychedelic substances, from hallucinogenic mushrooms to LSD.

Unlike other emotional conditions, PTSD is more of a national issue because often it is caused in part by trauma from combat and terrorism. It surfaced in a major way in the United States after the Vietnam War, but it has been the common byproduct of other more recent conflicts as well.

Experts estimate that about 11 to 20 percent of soldiers who have served in Iraq and Afghanistan suffer from PTSD, which Doblin said has provided an impetus for studies on MDMA as a form of treatment.

In this regard, the openness and daring of the Israeli Health Ministry is noteworthy in that it presents Israel, which has had its share of wars and tragedy as a country, prepared to assist its citizens suffering from PTSD using unconventional approaches.

This includes medical marijuana, and now MDMA, which has not yet received official approval for therapeutic use.

Following trials on adults, Doblin said, the FDA is seeking to conduct research on treatment of PTSD among patients aged 12 and 17. In addition, a further study is expected with 107 participants in a prior trial to determine whether improvements in their emotional state also resulted in a reduction in physical illnesses.

For her part, Ben-Gershon of the Israeli Health Ministry expressed her belief that the results of the upcoming compassionate use treatment and the next clinic trial in Israel will be decisive in giving physicians and therapist's confidence in MDMA.

If the results are positive, she said, it will not only address the needs of PTSD sufferers, but also generate hope that it could be a means of treating a broader range of mental disorders.

"In the United States, they are already doing studies on the use of MDMA in couples' therapy and with people on the autism spectrum to improve communications and help them understand social situations better," she said.