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MDMA and psilocybin considered in Australia for psychotherapy use

- Damon Cronshaw



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A psychiatrist has called for people suffering from treatment-resistant post-traumatic stress disorder [PTSD] to be allowed access to MDMA-assisted psychotherapy.

Dr Stuart Saker, whose practice is based in Toronto near Newcastle, NSW, said many of his patients were military veterans and emergency service workers.

Dr Saker said research showing the benefits of this therapy meant these people in particular would "demand this treatment".

His comments come as the federal Therapeutic Goods Administration (TGA) considers an application from Mind Medicine Australia to reschedule MDMA and psilocybin for use in the treatment of mental illness.

MDMA is also known as ecstasy, while psilocybin is a psychedelic compound found in mushrooms.

The historical moral panic and stigma around these substances is being transformed in the US and elsewhere across the world.


Medical research and clinical trials have shown these molecules have remarkable capacity to treat mental illness.

"Ideas about these medications are fundamentally changing," said Dr Saker, an Army Reserve medical officer, who has been deployed in war and humanitarian missions.

Dr Saker said the evidence showed that two or three sessions of assisted therapy with these substances led to 70 per cent of participants experiencing "full symptom remission".

"So they don't even have the condition anymore. There's not too many treatments in medicine that claim to be that effective," he said.



 Well Educated: Dr Stuart Saker, a Toronto psychiatrist, has done MDMA-assisted psychotherapy training. Picture: Simone De Peak

Dr Saker, who did MDMA-assisted psychotherapy training in Israel, is planning to use the substances for his patients.

"I'm in the process of applying for patients to get TGA approval to have MDMA-assisted psychotherapy for PTSD and psilocybin-assisted psychotherapy for major depressive disorder," he said.

He believes the TGA should reschedule the medicines.

"The people who I see with these conditions have already tried all the antidepressants," he said.

"They've already tried magnetic treatment and electrical treatment. They're desperate and, by definition, are treatment resistant."

He said the substances should be "reserved for the most treatment-resistant, desperate, unhappy patients who will try anything".

"The only people I would propose to go through this are dedicated patients who've tried everything and been really compliant and co-operative with treatment," he said.

A psychedelic compound named ayahuasca and a dissociative hallucinogen named ketamine are also being used in the US to treat mental illness and addiction.

"I've got patients who have flown to the United States for ketamine treatment for major depressive disorder. They've gone to LA because it's not available in Australia," Dr Saker said.

"People with PTSD are going to South America for ayahuasca ceremonies. These people are desperate and existing treatments are inadequate."


Many believe it is past time for the stigma around these types of substances to be discarded.

"If you look at this stuff historically, it basically got shut down with LSD in the '60s," Dr Saker said.

"[Former US president] Richard Nixon wanted to shut down the hippies and their free love and opposition to the Vietnam War. That's something political, not something scientific."





 Therapeutic: The TGA is considering a proposal to use MDMA for assisted psychotherapy for people with post traumatic stress disorder [PTSD].

He said MDMA treatment had therapeutic effects because "it makes the people taking it feel very connected to other people".

"That seems to facilitate the psychotherapy for PTSD, where people are very disconnected from other people and see other people as dangerous, hostile and threatening," he said.

"The psilocybin treatment for depression takes people on a journey where they can understand themselves a bit better. This reanalysis can act as a reset to the brain."

Psilocybin and MDMA are proposed to be rescheduled in Australia from Schedule 9 to Schedule 8 of the Uniform Scheduling of Medicines and Poisons. This rescheduling will more easily enable clinical treatment with these compounds.

This would include psilocybin-assisted therapy for Australians suffering from "depression and anxiety disorders and substance abuse", the application said.

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It could also potentially treat other illnesses such as anorexia nervosa and obsessive-compulsive disorder.

Treatment with psilocybin or MDMA would be done through psychiatrists and specialist physicians in "strictly medically controlled environments".

"In controlled settings there have been no major adverse events and minor side effects related to MDMA resolve within a few days," the application said.

"Further, medicinal MDMA does not produce dependence."

The proposed changes will not affect existing legal controls on illicit use or supply.

Researchers warn that people with personality disorders or conditions such as schizophrenia shouldn't use psychedelics. Medical professionals screen out such people from involvement in this type of therapy.


Newcastle MP Sharon Claydon said the TGA was independent to "ensure that it's science, rather than politics, that determines what therapeutic treatments are available in Australia"

politics, that determines what therapeutic treatments are available in Australia .

"We are on the brink of a mental health crisis, with record numbers of people reaching out to support organisations or seeking professional care," Ms Claydon said.

"If the Therapeutic Goods Administration determines that this treatment is safe and effective, I see no reason why it should be withheld from Australians who might benefit greatly from using it in a medically controlled environment."



 Compassionate Therapy: A participant in psychedelic-assisted therapy with two professionals guiding him. Picture: Multidisciplinary Association for Psychedelic Studies

Mind Medicine Australia's application to the TGA cited the research of Johns Hopkins University School of Medicine Professor of Psychiatry Roland Griffiths.

The work of Dr Robin Carhart-Harris, Head of the Centre for Psychedelic Research at Imperial College London, was also cited.

Their research found that psilocybin-assisted therapy can lead to "remission in 60 per cent to 80 per cent of cases of anxiety and depression".

"Existing treatments lead to remission in a maximum of 35 per cent to 42 per cent of cases."

The application also cited research about MDMA.

In a controlled setting, MDMA-assisted psychotherapy supports patients in "reprocessing traumatic and painful memories", making it effective for treating PTSD and addictions associated with trauma.

"There is strong evidence for the safety and efficacy of MDMA-assisted psychotherapy for the treatment of PTSD."

The application added that the US Food and Drug Administration had granted psilocybin and MDMA "breakthrough therapy designations".

This expedites drug development to "treat serious conditions and fill an unmet medical need".



 Mushrooms: Psilocybe cubensis is known to grow in cow pats. It contains the hallucinogen psilocybin. Picture: Alan Rockefeller

Psilocybin had been granted this status in the US as part of therapy for treatment-resistant depression and major depressive disorder.

"The FDA acknowledges the potential for these therapies to offer significant improvements over existing therapies. In a medically controlled environment, psilocybin-assisted therapy is safe, non-addictive and there is no increase in risk for mental ill-health.

"Psilocybin-assisted therapy has yielded remarkable clinical results for depression and anxiety in numerous trials at leading universities internationally."

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MDMA's transition to a prescription medicine in the US could be expedited, "subject to positive outcomes from current Phase 3 trials".

Mind Medicine Australia said treatment innovation in Australia's mental health sector was "desperately needed to reduce the burden of mental illness in this country".

"In November last year the Productivity Commission reported that one in five Australian currently had a chronic mental illness, a ratio that will almost certainly have deteriorated further with the bushfires earlier this year and the current COVID-19 pandemic.

"Suicides and self-harm are also increasing."

Mind Medicine Australia chairman Peter Hunt is advocating for a "proactive approach to broadening the treatment options available for people who have a mental illness".

"The rescheduling of psilocybin and MDMA will represent a giant leap for innovation in mental healthcare, not only in Australia but globally," he said.

Ethics Centre executive director Dr Simon Longstaff, a Mind Medicine Australia board member, said: "We should not allow the prejudices of the past to deny relief in the present".

"If these medicines are safe and effective when applied in a clinical environment, as current research suggests, then Australian governments have an obligation to make them available."