

MDMA-assisted psychotherapy for bushfire victims Fast-tracked access needed for breakthrough PTSD treatment

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It is estimated that 800,000 Australians suffer from post-traumatic stress disorder (PTSD). Mental health experts predict this staggering figure will rise sharply as a result of the trauma experienced by families and first responders who have had their lives or safety threatened by the catastrophic bushfires this summer.

In response to this mental health crisis, Mind Medicine Australia (MMA) has called for the fasttracking of access to MDMA-assisted psychotherapy for the treatment of PTSD. MMA is a not-forprofit organisation established to promote the development of research-backed and regulatoryapproved Medicine-Assisted Therapy in Australia.

Doctors typically treat people who have PTSD with psychotherapy and pharmaceutical medicines. But the medications can often produce unpleasant side effects and show a mere 20%-30% success rate for patients. Exposure therapy is more successful, providing relief from PTSD in around half of cases. However, the treatment process can be long and extremely gruelling, causing many patients to drop out.

In contrast, recent clinical trials of MDMA-assisted psychotherapy in the United States have shown to relieve PTSD immediately after just three active dose sessions for 54% of participants. A 2018 study specifically in first responders and veterans showed that patients improved further at a 12-month follow up with 67% of them in remission. The results of a separate study showed than an astounding 76% of participants did not meet the clinical diagnostic criteria for PTSD a year after the conclusion of treatment.

The research has been so promising that the American Food and Drug Administration (FDA) granted MDMA-assisted psychotherapy Breakthrough Therapy status in 2017. The FDA is expected to give full regulatory approval for the treatment in the next few years after the current Phase 3 trials are completed. Earlier this month, however, an Expanded Access Program was authorised by the FDA that permits the use of MDMA-assisted psychotherapy in the United States this year, ahead of the conclusion of clinical trials. Similarly, Israel, Switzerland, and Canada have recently begun Compassionate Use Schemes that enable PTSD patients to access this therapy.

Peter Hunt AM, Chair of MMA, says that Australia needs to follow the lead of these countries quickly. *"These medicines have been proven to be very safe when used as part of psychotherapy in a clinically controlled environment. The Australian Therapeutic Goods Act allows the use of medicines which are not listed on the Therapeutic Goods Register under the Special Access Scheme. Australia needs to act now and expedite the availability of MDMA-assisted psychotherapy through this program to relieve the suffering of bushfire victims and others with PTSD."*

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Tania de Jong AM, Executive Director of MMA, agrees that an urgent shift in approach is needed. "The Australian government has allocated \$76 million for distress counselling and mental health support for those affected by the bushfires. Despite the best of intentions, the current treatment methods don't help all people who have developed PTSD. The evidence shows that MDMA-assisted psychotherapy not only works but, in the long term, will also be highly cost-effective for taxpayers."

Bushfire-affected people who have developed PTSD may experience ongoing feelings of panic or extreme fear. Without effective treatment, the debilitating symptoms can last for many years or even a lifetime. It is a condition that can act as a catalyst in a person for depression, substance abuse, and suicide, and is linked to unemployment, homelessness, and family violence.

Statistics show that 10% of first responders have PTSD, and a third of them endure high psychological distress. They have suicidal thoughts at twice the rate of adults in the general population, and one first responder takes his or her own life every six weeks.

According to the Productivity Commission's 2019 Mental Health Report, the total cost of mental illness and suicide to the Australian economy is \$180 billion per year.

MDMA used in Medicine-Assisted Therapy and within a clinically controlled environment is not the street drug Ecstasy. Substances sold illegally often have adulterants and are usually taken in risky settings with high doses.

The medicine is not a cure in itself but a facilitator for the therapeutic process. It decreases activity in the amygdala, part of the brain associated with traumatic memory, and reduces fear and defensiveness while increasing empathy, trust, and safety. Only two or three active dose sessions are needed in contrast to antidepressant treatments that usually require daily medications. Due to the ease of the treatment process, patient adherence rates are much higher with MDMA-assisted psychotherapy compared to other psychotherapies, like exposure therapy.

Like MDMA, mounting clinical research indicates that psilocybin, a naturally occurring compound derived from what is colloquially known as magic mushrooms, can provide highly effective solutions for various mental illnesses when used in a clinically controlled environment in conjunction with psychotherapy. Studies show that both these medicines are physiologically safe and are not addictive. Universities that have researched these medicine-assisted psychotherapies include Harvard, Oxford, Cambridge, NYU, Imperial College, Yale, and Kings College, among many others.

Mind Medicine Australia is co-funding Australia's first clinical trial of Medicine-Assisted Therapy at St Vincent's Hospital in Melbourne. Participating palliative care patients experiencing depression and anxiety are being treated with psilocybin. Mind Medicine Australia anticipates that more clinical trials will be announced at major research institutions in Australia soon.

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MMA was founded by social entrepreneurs Peter Hunt AM and Tania de Jong AM following their successful experience setting up other charities and working with people diagnosed with a mental illness. Visit <u>mindmedicineaustralia.org</u> for comprehensive information about the organisation.

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