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Drug and Alcohol Information
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What are psychedelic assisted therapies?

Overview

You may have heard about psychedelic assisted therapies, which have received increasing attention in the media as potential mental health and substance use treatments. In these therapies, drugs like MDMA and psilocybin are used in controlled therapeutic settings alongside other established therapies, such as talk therapy, to treat conditions including severe forms of depression, PTSD, and anxiety.

The drugs are highly regulated, and manufacturers, suppliers, and medical practitioners need to comply with strict requirements. For example, the drugs can only be taken under the supervision of at least one medical professional in a clinical setting. Research on these drugs is still in its early stages. While there is some evidence to suggest potential benefits of psychedelic assisted therapies in controlled settings, it is important to be aware of the limitations of current research and the specific contexts in which these drugs are prescribed.

There have been recent changes to Australia's regulation of psychedelic assisted therapies:

Key changes to Australia's regulations

- As of the 1st of July 2023, MDMA and psilocybin are nationally recognised as medicines and can be prescribed in strictly controlled contexts and conditions. However, currently there are no approved MDMA or psilocybin containing products on the Australian Register of Therapeutic Goods (ARTG)
- **Only** registered and authorised psychiatrists can prescribe them
- MDMA can **only** be prescribed to treat PTSD
- Psilocybin can **only** be prescribed to treat treatment-resistant depression (when someone has tried at least 2 anti-depressants and shown no improvement)

More information can be found here: https://www.tga.gov.au/news/blog/understanding-changes-mdma-and-psilocybin-access

It is important to know that these drugs remain illegal for all other purposes. It is still illegal in most states and territories in Australia to possess these drugs. Even small amounts for recreational use can be met with criminal punishments and fines.

If psychedelics are illegal – and potentially harmful – why are they being used in treatment?

Psychedelic assisted therapy is only considered in very limited circumstances where other treatments have not worked. Psychedelic assisted treatment will only be offered if after a medical review, the treating psychiatrist considers that the potential benefits outweigh the risks to the patient.

It's crucial to highlight that psychedelic assisted therapies are not about the drugs alone. Rather, they are a combination of the psychedelic experience and skilled therapeutic support, all done in safe and highly controlled settings. When used in treatment, the drug is strictly controlled to ensure appropriate purity and strength. The patient is also under strict medical supervision, which helps to decrease risks. While these treatments may be promising, it doesn't mean these drugs are safe to use recreationally.

When these drugs are taken outside controlled settings there are increased risks of adverse events happening.

Illegal drugs lack quality control and are prone to contamination. They often contain other substances and are not as pure as those used in treatment. This increases the risk of unpredictable and potentially dangerous health effects, including overdose.

Visit https://theknow.org.au/ for timely information on drug warnings. Read our 'How to help someone who has taken a drug' factsheet to learn more.

So, what are psychedelics and why are they being used alongside therapy?

Psychedelics (or hallucinogens) are a group of drugs that can cause large changes in the chemicals in your brain. This can affect how you see and feel reality, causing things like hallucinations. Two psychedelics being used in therapy are MDMA (ecstasy) and psilocybin. Below we will explain these substances in more detail.

Psilocybin

Psilocybin is a natural psychedelic found in many mushroom species around the world. Psilocybin can bring about hallucinations such as seeing vivid colours, distorted shapes and seeing or hearing things that aren't there. People who use Psilocybin report having reflective thoughts and feeling emotions differently during intoxication. These effects can vary widely among individuals and misuse can lead to anxiety, nausea, or a challenging experience known as a "bad trip".



Follow the link to find out more about psilocybin and other psychedelics: https://positivechoices.org.au/teachers/hallucinogens-factsheet

Early research with small sample sizes suggests that psilocybin assisted therapy can be safe when delivered in a controlled environment. It also shows promise in reducing the severity of depression symptoms in patients with major depressive disorder (MDD), a severe form of depression, when compared to patients taking a placebo drug with therapy. In clinical trials, a placebo drug looks and tastes like the drug being tested but does not have any effects. Researchers compare the results from participants who took the placebo to results from participants who took the drug (i.e., psilocybin) to rigorously assess the effects of the drug. There is also early research for psilocybin therapy compared to placebo in reducing end of life anxiety symptoms in patients with life threatening cancer.

When used medically, psilocybin is given as part of a highly structured psychedelic assisted therapy program. It is thought that psilocybin assists treatment by helping the patient trust the therapist and make them more open to flexible thinking. This type of treatment is only approved for patients who have depression that is not improved by other treatments. There are several approaches to treating depression that are more widely available. For more information, visit https://www.healthdirect.gov.au/depression#treatment.

MDMA



MDMA or ecstasy causes the body's central nervous system to speed up. Many users report a sense of euphoria, feeling more energised and emotionally open, and increased relatability to others. It's important to note that MDMA can also have risks, including nausea, dehydration and overheating. Other short-term effects can include anxiety and paranoia.

Follow the link to find out more about MDMA: https://positivechoices.org.au/teachers/ecstasy-and-mdma-factsheet

Recent research on MDMA assisted therapy found large reductions in PTSD symptoms when compared with a placebo drug and therapy among a diverse sample. Everyone who was given MDMA in this trial experienced negative side effects during treatment including muscle tightness, nausea, and decreased appetite. When used medically, MDMA is delivered in a highly controlled environment to support structured therapy programs, rather than as a treatment by itself. Researchers think it may help improve the therapy process by increasing trust between the therapist and patient. Its activity in the brain could potentially help to reduce fear or negative emotions when revisiting traumatic events in patients with PTSD, which is useful for processing these events.

Research limitations and cautions

In 2024, the United States Food and Drug Administration (FDA) rejected the first ever application for approval of MDMA assisted therapy for PTSD from a psychedelic drug developer. This decision was made after an advisory panel concluded that more evidence was needed to determine the effectiveness of this treatment. They also found that the benefits of this application did not outweigh the risks.

There are some problems with current research on psychedelic assisted therapies, due to how the studies have been designed and conducted. When testing the effects of treatments, it is important that the participants don't know if they are receiving the drug or not. This is called 'blinding', and it helps researchers know if a person's treatment response is due to the drug or something else. If the participant knows they have taken the drug, then the results of the study might be affected by the person's thoughts and beliefs, rather than the drug itself.

With psychedelic drugs, most people can tell they received the real treatment as they feel the psychedelic effects. This can impact the results by overestimating the drug's effectiveness and make findings less valid if not appropriately handled.

In addition, a scientific journal called Psychopharmacology took back three papers about MDMA assisted therapy conducted by the psychedelic drug developers. They did this because they were concerned about how the studies were conducted including ethical violations and authors not fully declaring conflicts of interest.

In summary

While psychedelic assisted therapy research is still in early stages, some evidence suggests that these therapies have the potential to be safe and effective tools for improving mental health care among targeted clinical population groups in a controlled setting, when other treatment options have not worked. Small sample sizes in controlled clinical settings makes it hard for researchers to be sure that the results would apply to larger, more diverse populations. Furthermore, gold standard practices for conducting drug treatment trials are difficult to achieve for psychedelic assisted therapy, because the effects of the drugs mean participants can tell whether they received the drug, or a placebo. As psychedelic assisted therapies are relatively new, more research is needed to determine whether they are effective treatments, who they might be effective for and if benefits of these treatments can last over the longer term.

This blog post was developed by Zachary Bryant and the Positive Choices team.

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