

Psychedelic medicine is on its way, but it's not 'doing shrooms with your shrink.' What you need to know

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Many people in Australia, including psychiatrists, were surprised when earlier this year the medicines regulator <u>down-scheduled</u> MDMA, known colloquially as ecstasy, and psilocybin, from magic mushrooms.

This means that under certain circumstances from July 1, authorized



<u>stress disorder</u> and psilocybin to treat depression that has not responded to other treatments. Patients must also undergo psychotherapy (talking therapy).

It all sounds very certain but it's not really.

Beware the hype

The Therapeutic Goods Administration decision has left a lot of questions unanswered about how the new scheme will be implemented and operated, both effectively and safely.

There are a small number of countries where <u>psychedelic</u>-assisted therapies are used outside <u>clinical trials</u>—in a very limited manner. However, this is the first time a <u>national government</u> has altered the way these substances are formally classified.

So the world is watching closely how "psychedelic-assisted therapy," as it's officially called, is rolled out in Australia.

It's a hot topic, with much <u>public interest</u>. But for researchers, there are concerns the hype is getting way ahead of the research.

The first steps

The Royal Australian and New Zealand College of Psychiatrists this week <u>released guidance</u> to their members about how this would work in practice.

As researchers in this field, we helped develop these guidelines. They cover topics such as <u>patients</u>' suitability for this therapy, and how to administer and monitor it.



The guidelines also stress the importance of patient safety and appropriate training for prescribers, and advocates for continued research.

What does this mean for patients?

This has several implications for potential patients:

- their existing <u>psychiatrist</u> may not be authorized to prescribe these psychedelics. So patients will have to ask their psychiatrist or GP for a referral to one who is
- the psychiatrist authorized to prescribe these psychedelics will need to assess whether the therapy is suitable for each individual patient. This involves a detailed and comprehensive assessment. If the treatment is suitable, several sessions of further assessment and therapy are required before the actual dosing session
- patients will be informed of what to expect before, during and after treatment, and need to give consent to proceed. We also recommend psychiatrists tell patients this therapy is not guaranteed to work, and provide patients with a clear account of the risks and possible negative side effects of psychedelic medications.

Expectations are high, but clear evidence is lacking

Despite a growing <u>body of evidence</u>, psychedelic-assisted therapies are in their infancy.

In a time when demand for <u>mental health services</u> far outstrips supply, exaggerated promises about the effectiveness of these drugs, before the



research results are in, has many researchers worried. Patient expectations remain high but good clear evidence is still lacking.

Australian research is just getting under way and so far most psychedelic research has been done overseas. Yes, early findings have been <u>quite</u> <u>promising</u>, but numbers are small, long-term follow-ups sparse, and potential risks and dangers still need to be explored.

Destignatizing these drugs has allowed us to begin our research, but sensationalizing their effectiveness has the potential to disappoint and even harm patients because we really don't know enough about how they work and who is suitable for this treatment.

Psychedelic-assisted therapy is no miracle cure. Espousing the benefits without a thorough examination of the risks and limitations is not only a misrepresentation of the science, it is arguably unethical.

Very few psychiatrists have had much experience in this fascinating but challenging field. We still have a lot to learn about the use of psychedelic medicines to treat psychiatric illness.

Undue haste in translating psychedelic-assisted therapy conducted in clinical trials to community clinics could affect how well these treatments work and their safety. Outside clinical trials, patients will also need to shoulder the cost of this therapy, raising equity issues.

There's potential for harm

Psychedelic-assisted therapy is not simply "doing shrooms with your shrink."

There is potential for psychedelic substances to cause fear, panic or cause psychological damage if given to susceptible and <u>vulnerable people</u>



who have been inadequately screened or assessed.

Paranoia, traumatization, worsening depression, and even suicidal behavior, among other <u>serious side-effects</u>, <u>have been observed</u> in some cases.

So we need ongoing monitoring of outcomes, including adverse events.

We also know psychedelic substances render patients particularly vulnerable. Boundary issues and safeguards are vital considerations for patient safety, particularly when patients are under the influence of the psychedelic drug. For instance, it is important to discuss and agree with patients beforehand about the nature and timing of any touch during treatment sessions, so any touch is appropriate and done with full informed consent.

An exciting prospect

Despite the potential harms, we remain excited at the prospect of psychedelic-assisted therapy becoming an established treatment to help a select group of patients.

But we want to do this in a safe, controlled and sustainable manner.

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