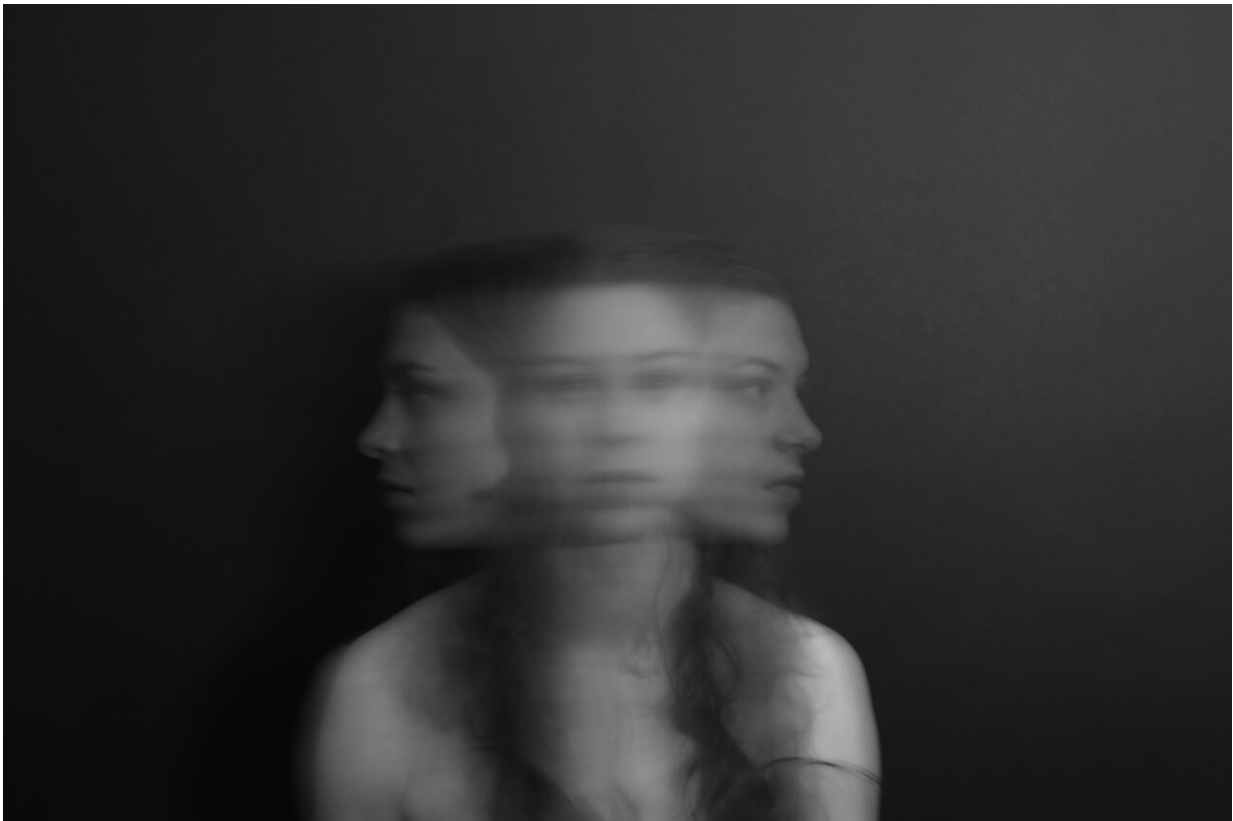


From promise to practice: A dose of reality for psychedelic therapies

June 16 2023



Credit: Unsplash/CC0 Public Domain

Psychedelics stand at a pivotal crossroad in mental health, offering the prospect of novel therapeutic avenues to address multiple mental conditions, from treatment-resistant depression to post-traumatic stress

disorder (PTSD). However, their mind-altering properties present unique ethical and clinical challenges.

In a newly published article in *Nature Medicine*, leading psychiatrists, psychologists and psychotherapists highlight the importance of protecting patients during these vulnerable states of altered consciousness and the imperative for regulatory frameworks and [collaborative efforts](#) to fully realize the [potential benefits](#) of this emerging treatment paradigm.

The exploration of alternative therapeutics for hard-to-treat [mental health](#) disorders has brought into focus an array of [psychedelics](#) such as psilocybin, present in magic mushrooms, and LSD, substances once associated more with counterculture than [clinical practice](#).

Alongside atypical psychedelics like ketamine and MDMA, these substances are increasingly being recognized for their potential therapeutic attributes. For example, synthetic psilocybin has shown promising results in alleviating symptoms of depression and anxiety associated with cancer diagnosis, while its efficacy is being investigated in relation to conditions such as obsessive-compulsive disorder, eating disorders, and [substance use disorders](#).

Moreover, while the subjective experiences they elicit may differ, both typical and atypical psychedelics are generally deemed safe with limited potential for abuse. However, a seamless transition from [clinical trials](#) to regular clinical practice is by no means guaranteed. As Albino Oliveira-Maia, senior author of the article and head of the Champalimaud Foundation's Neuropsychiatry Unit, notes, "Up until now, [psychedelic](#) therapies have largely been confined to the realm of research and clinical studies. But this looks set to change. We're already witnessing off-label use of ketamine, once solely viewed as an anesthetic, in treating depression and substance use disorders, despite the lack of clear

guidelines, formal approval from [regulatory agencies](#), and recommendations regarding psychological support."

Unlike most drug treatments, psychedelics are typically coupled with psychotherapy to safeguard patients and potentially enhance clinical effectiveness through shaping the drug-induced subjective experiences. The authors emphasize the necessity of assessing the clinical effectiveness of the accompanying therapy.

"If psychotherapy during the psychedelic experience offers substantial additional benefits to the patient, defining and standardizing optimal therapeutic procedures for these dosing sessions becomes essential," says Oliveira-Maia. "Our goal is also to ensure that the promise of psychedelics does not come at the expense of patient safety." Psychedelics can provoke heightened suggestibility or feelings of intimacy, which may increase vulnerability to potential abuse and boundary transgressions in the therapist-patient relationship.

An alleged example of such a transgression occurred in a Canadian clinical trial of MDMA-assisted therapy for PTSD, where a participant and her unlicensed therapist were involved in an out-of-court settlement for a sexual assault claim. Such incidents underscore the necessity for certified and professionally trained practitioners, regulatory oversight, and enhanced informed consent procedures to address possible use of touch and patient susceptibility during altered states of mind.

"This will demand a collective effort," says co-author Ana Matos Pires, Director of the Mental Health Department at Unidade Local de Saúde do Baixo Alentejo and Member of the Board of Psychiatrists at the Portuguese Medical Association. "Not only will it involve the physicians who prescribe the treatment and the psychologists who administer it, but also a range of other stakeholders at national and international levels, from regulatory bodies like the US Food and Drug Administration and

European Medicines Agency, to policy makers, ethics boards, pharmacists, nurses, and of course, the patients themselves."

In Portugal, researchers working with psychedelics are already engaging with professional societies of psychiatrists and clinical psychologists, as well as ethical authorities, to preemptively address the regulatory challenges that may surface if these psychedelic treatments become mainstream.

"We see our [proactive approach](#) serving as a blueprint for other countries preparing for the potential incorporation of psychedelic treatments into clinical practice," says Matos Pires. "Health literacy is also critical in this area. It's crucial that we clearly inform the public about this kind of treatment. Psychedelic therapies are not a panacea but another tool with which to treat mental illness."

Many aspects remain to be clarified, from determining appropriate dosages and antipsychotics to counter adverse effects, to identifying the ideal settings for treatment, whether within traditional hospital environments or alternative therapeutic spaces. Time, though, is of the essence. Recently, Australia declared its intent to authorize the therapeutic use of MDMA and psilocybin starting July 2023, while the FDA could approve the use of MDMA for treating PTSD as early as 2024.

"We agree on the potential benefits of psychedelics," says co-author Luís Madeira, President-elect of the Portuguese Society of Psychiatry and Mental Health, and Counselor of the National Council of Ethics for the Life Sciences. "Nevertheless, it's vital to acknowledge the associated challenges and avoid rushing the process. Given that trials typically pair psychedelics with therapy, further research will be needed to better understand the individual effects of both the drug and the therapy. It's plausible that one may prove more efficacious than the other."

One notable challenge Madeira brings up is the difficulty of conducting unbiased double-blind studies, as the distinct psychoactive effects make it obvious to both participant and researcher who has received the treatment or placebo. Additionally, the question of accessibility in the public health system arises, given that each psychedelic experience can last eight hours and usually involves two trained therapists. "A potential solution," explains Madeira, "might be group therapy, allowing therapists to treat multiple patients simultaneously, thereby reducing costs and making the treatment more feasible within public health systems."

The article's first author Carolina Seybert, Clinical Psychologist at the Champalimaud Clinical Center, stresses the need for an agile process. "These protocols need to be flexible and dynamic as our understanding of these therapies evolves. In a rapidly changing field like this, in which our knowledge base is constantly updating, it's key that our guidelines and regulations are not just robust, but also adaptable. We need a uniform framework in place that can be modified as new information comes in. If we leave this process to the self-regulation of individuals, the patient's experience may vary substantially from one case to the next."

In a sense, our exploration of psychedelics in mental health mirrors the very nature of the treatment itself, a venture into uncharted territory and new possibilities. The authors' article provides a timely compass and a lucid appreciation of the ethical and regulatory realities ahead.

More information: Carolina Seybert et al, Psychedelic treatments for mental health conditions pose challenges for informed consent, *Nature Medicine* (2023). [DOI: 10.1038/s41591-023-02378-5](https://doi.org/10.1038/s41591-023-02378-5)

Provided by Champalimaud Centre for the Unknown

Citation: From promise to practice: A dose of reality for psychedelic therapies (2023, June 16)
retrieved 28 April 2024 from

<https://medicalxpress.com/news/2023-06-dose-reality-psychedelic-therapies.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.