Canadian Psychiatric Association
Association des psychiatres du Canada

Perspective

The Canadian Journal of Psychiatry / La Revue Canadienne de Psychiatrie
2024, Vol. 69(5) 309-313

DOI: 10.1177/07067437231225937
TheCJP.ca | LaRCP.ca
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Informed Consent to Psychedelic-Assisted Psychotherapy: Ethical Considerations

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Keywords
psychedelic-assisted psychotherapy informed consent bioethics

Introduction

Psychedelic-assisted psychotherapy (PAP) refers to an emerging and experimental treatment modality which involves the administration of psychedelic substances in conjunction with psychotherapy. The most commonly studied psychedelics include psilocybin, lysergic acid diethylamide, and 3,4-methylenedioxy-methamphetamine (MDMA). In combination with psychotherapy, these substances are being evaluated for indications including post-traumatic stress disorder, major depressive disorder, and substance use disorders. Currently, the PAP model typically includes 3 types of sessions: preparatory, medication, and integration.[1]

The psychedelic experience itself appears to have a central role in this emerging treatment, although this is subject to debate.[2,3] Numerous studies involving different psychedelics and clinical indications suggest that the quality of the psychedelic experience mediates both short- and long-term benefits in PAP.[4] While the potential for psychedelic experiences to bring about lasting benefits has received much attention, there is also emerging literature on challenging psychedelic experiences, with some evidence that they may cause enduring harm.[5] Best practice suggests that therapists should support participants in working through difficult material during psychedelic sessions to help participants achieve a resolution.[6,7] However, if participants cannot be adequately supported through these challenging experiences, they may seek relief in one form or another, including a request to terminate the psychedelic session.

Publicly available documents such as clinical trial protocols, therapy manuals[8] trial supplementary materials, and the recently published professional practice guidelines from the American Psychedelic Practitioners Association[7] refer to the importance of supporting participants experiencing anxiety, including the methods by which therapists may support participants in a session. These materials also allude to rescue medications for participants experiencing more severe distress. However, discussions about how decisions are made regarding rescue medications remain vague. Notable exceptions include the Yale Manual for Psilocybin-Assisted Therapy of Depression[9] which states, "using any rescue medications will be a joint decision, not a unilateral decision. However, in the case of an unresolvable difference of opinion, the participant must accept the clinical judgment of the study physician and therapists."

More broadly, publicly available codes of ethics and related guidelines for psychedelic therapists and researchers tend to describe important considerations around informed consent and associated ethical responsibilities. The Canadian Psychological Association's guiding document outlines a code of ethics for interacting with participants receiving psychedelic treatment is a notable example.[10] Indeed, some of these documents describe professional and ethical practices in PAP, while others emphasize clinical procedures in PAP. A consistent limitation, however, is a nuanced articulation of the complexities of informed consent—including the withdrawal of consent—*during* the psychedelic session, as well as the important questions about whether, how, who decides, and when a psychedelic session ought to be terminated. These questions are critical for psychiatric practice given the potential effects of psychedelics on decision-making capacity as the unique and unpredictable psychedelic experience can create situations of intensified vulnerability for some participants.

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In this Perspective article, we focus on capacity and informed consent to PAP and explore issues related to the consent process during therapy. We conclude by considering how to improve the informed consent process, with an emphasis on mitigating risk prior to the psychedelic experience.

Informed Consent in PAP

Informed consent is the practical expression of the ethical principle of respect for autonomy.[11] Informed consent is defined as the process in which a clinician informs a patient of the risks, benefits, likely consequences, and alternatives to a proposed treatment. A necessary component of informed consent is that the patient has the capacity to make the treatment decision, namely that they are able to understand the treatment decision and appreciate the consequences of the decision, including not making the decision. Decisions must be made voluntarily. The threshold of capacity required to consent to a particular treatment should be proportional to the level of risk associated with the treatment.

Given that psychedelics can induce powerful nonordinary states of consciousness and increase suggestibility, challenges surrounding the informed consent process in PAP have begun to receive attention.[12] For example, Smith and Sisti[13] suggest that a process of "enhanced consent" be undertaken prior to PAP, characterized by special attention to the shifts in personality and values that can follow a psychedelic experience, the possible mental health side effects of psychedelics, and the possible use of therapeutic touch during treatment. However, Jacobs argues that owing to the particular effects of psychedelics—namely, mystical and ego-dissolution experiences which can occur acutely after administration and longer-term shifts in identity and values—the typical standards for informed consent may not be feasible.[14]

Issues of capacity and consent *during* the psychedelic experience have received less attention. Individuals using psychedelics often experience profound acute changes to their sensorium along with alterations in mood, detachment from the body, and distortions of their sense of self, time, and reality.[15] Consequently, it may be difficult for patients to appreciate the risks and benefits of terminating the session during the psychedelic experience. It may also be difficult for observers to predict or interpret the internal process and distress of patients during sessions, as their observable behaviour may not be representative of their inner experience.[15]

There has been little systematic research on negative psychedelic experiences or "bad trips," the definition of which remains unclear.[16] One attempt to characterize bad trips is the Challenging Experience Questionnaire, which outlines 7 dimensions of such experiences: physiological distress, grief, fear, insanity, isolation, death, and paranoia.[15] Consumers of psychedelics describe a host of challenging experiences, including re-exposure to past traumas or exposure to traumatic experiences outside of their awareness; paranoia; and fear of being "stuck" in an altered state.[17] Bad trips have been described as beginning as any other experience before participants encountered difficulty which they felt they could not escape.[18] Bad trips were often a consequence of the "set and setting"[19] and a lack of appropriate support. Still, most participants who experienced a bad trip defined it as an important turning point in their life history, and 1 participant described developing greater insights and a positive outlook.[18] Understandably, the potential for disturbing visual experiences, acute distortions of reality, and lack of control of both physical and mental states could lead to a patient requesting the termination of a session.

The potential risks associated with terminating a psychedelic session are not well understood. Although the current recommended approach is to conservatively manage a participant's distress with verbal reassurance, participants who pose harm to themselves or others may require intervention with medications (e.g., benzodiazepines or antipsychotics).[8] This also raises concerns about the potential use of invasive measures such as chemical and physical restraints. There are also well-known risks of using terminative medications such as benzodiazepines and antipsychotics, but their effects on participants using psychedelics have not been systematically studied. Terminating a session itself may carry risks. Patients who have an "incomplete" experience, for example, may not have the opportunity to adequately work through challenging material and arrive at a resolution. It is also unclear whether terminative measures may influence the incidence of hallucinogen-persisting perception disorder[20] or other enduring symptoms.

If the therapist alone determines whether and when to terminate the session, there is a risk of widening the power dynamic between the therapist and the patient. This could result in patients being more vulnerable to abuse—a risk of PAP that is receiving increasing attention. For example, during a phase 2 clinical trial involving MDMA, therapists were videotaped physically restraining a participant and cuddling and kissing her.[21] McNamee et al.[22] describe several factors that were found to lead to these abuses, including overly flexible protocols, use of unevaluated and controversial practices, and failures of oversight. The unpredictability of the psychedelic experience may alter or impair an individual's ability to consent or express themselves authentically in distressing moments. Therapists are thus in a position to exert undue influence on vulnerable patients in a heightened state of suggestibility who cannot advocate for themselves.

Considerations for Strengthening the Informed Consent Process in PAP

PAP presents unique challenges related to autonomy, decision-making, and informed consent. Our interpretation of autonomy and decision-making is inherently relational, one that considers the social-situatedness of people's lives and individuals as interdependent with others including their families, communities, and environment. A relational

perspective is also attendant to power dynamics between patients and therapists, and how social conditions can both enhance or undermine autonomy.[23] With this orientation, we consider the following options for helping to strengthen informed consent in the context of PAP:

(1) **Psychiatric advance directives (PADs)**: PADs enable patients with mental illness at a time when they have the capacity to express treatment preferences for future mental health crises when they cannot express capable wishes and preferences.[24] The goal of PADs is to promote patient autonomy and strengthen the therapeutic relationship by instructing a patient's health providers or substitute decision-makers on how to respond in times of crisis, deterioration, or loss of capacity. A "psychedelic advanced directive" could be informed by factors including previous experience with psychedelics, an intimate knowledge of one's mental health history and symptoms, and whom the patients trust to make decisions for them should they not be capable of doing so during PAP.[25] However, PADs are limited because they may contain unclear instructions, requests might not align with best practices, and they do not have legal weight in many jurisdictions.[24] Due to the expansive nature of psychedelics, it would be impossible to describe the potentially infinite possibilities of psychedelic experience, and then to define a patient's wishes regarding the response they desire in those highly specific situations. At a minimum, PADs may be a helpful starting point for discussion between the patient and PAP therapist about boundaries, wishes, and preferences, as well as a consideration of the patient's best interests more broadly.

(2) **Dynamic consent (DC)**: DC is an approach to informed consent that enables ongoing engagement and consent-related communication between individuals and their study therapists, rather than a 1-time event. This is the ethical ideal of informed consent to treatment generally, although it is not always protocolized or systematically included in studies and may not necessarily occur in practice.[12] DC is a process that allows patients to change their decision about PAP during treatment. For example, a participant may initially provide informed consent for PAP research after they are provided with the logistical details, potential benefits and harms, and alternatives. During the preparatory phase, the research team may revisit elements of PAP and the participant would have the opportunity to ask questions, reflect on and revise their decision. DC can further empower participants/patients to make important decisions throughout their treatment journey, including about issues that may arise during the psychedelic session such as containment of emotional distress or the use of terminative measures.

Furthermore, DC would also apply to the provision of therapeutic touch—a common aspect of PAP protocols[8]. Consider a scenario where a patient has not previously consented to touch, but in a distressing moment during the session, they seem to change their mind and request it. Although some patients may be capable of making this request under the influence of psychedelics, some have suggested that the precautionary principle be applied to such situations.[26] The precautionary principle is characterized by the adoption of protective measures when there is a suspected risk of causing harm before there is a complete scientific understanding of risk. Due to the lack of research on the benefits of therapeutic touch during PAP, a more risk-averse approach should be taken in such cases as the potential risks of unwanted touch outweigh the undetermined benefits. Conversely, should a patient consent to therapeutic touch prior to a psychedelic session, but withdraw consent during the session, therapists should withhold touch. Although there is a lack of clarity regarding a patient's capacity at that time, the foreseeable harms outweigh the undetermined benefits of providing touch.

(3) **Enhancing Informed Consent Through Trustworthiness:** Trust is a foundational value of the therapeutic relationship and is essential to the practice of PAP. Since patients are especially vulnerable in the context of PAP, additional duties are required in relation to protection from exploitation and other harms. Common characteristics of trustworthy health-care professionals include professional competence, honesty, and maintenance of therapeutic boundaries. Professional competence in PAP would include knowledge of the physical, psychological, and spiritual effects of psychedelics, understanding the principles of PAP, enacting the ethical principles of PAP, and addressing complications of PAP.[7] People who use psychedelics have highlighted predictability as a core component of trust, along with carers' ability to understand and anticipate their behaviours.[27] Additionally, a pre-existing relationship with the carers was cited as critical, as users expected to have a sense of safety in a vulnerable state.[27] These findings reinforce the importance that therapists demonstrate trustworthiness prior to any psychedelic treatment phases, as misplaced trust could lead to harm. Preparatory sessions provide a crucial opportunity for therapists to demonstrate trustworthiness to participants by establishing essential aspects of the set and setting while outlining the logistics of PAP. The discussion of possible experiences and methods of addressing challenging experiences during preparatory sessions should be considered an extension of the informed consent process.[13] It is also important to consider the importance of conveying information regarding the risks, benefits, and harms in a culturally responsive way.[28] People of colour are currently underrepresented in psychedelic research, which may limit the generalizability of results.[29] Culturally informed research designs can contribute to further demonstrating trustworthiness with providers, by helping to address health inequities, mitigating stigma, and having diverse research members that represent the population being served.[30]

Conclusion

As the evidence for PAP develops, the informed consent process, treatment protocols, and best practices for ongoing

care are evolving as well. There are important ethical dimensions for informed consent to PAP that need to be considered —including revocation of consent, incapacity, and contingency plans. It is essential that further research explores novel consent models, risk mitigation, and protective measures during the psychedelic experience to ensure we are treating participants effectively and ethically. The specific issue of terminating psychedelic sessions also warrants careful attention and systematic study. Detailed case reports involving challenging psychedelic sessions and how they are managed would be useful in this regard; ideally, such reports would include both therapist and patient perspectives. Long-term follow-up on the sequelae of terminating psychedelic sessions should be systematically researched if these avenues are to be offered to patients in future clinical practice.

Notably, all 3 strategies we have considered for strengthening informed consent in this Perspective article occur *before* the psychedelic experience itself. As drug companies, insurance providers, and regulatory agencies consider scaling PAP from the clinical trials context to wider applications, the importance of ethical considerations cannot be overstated. With increasing pressure to condense the non-drug elements of PAP, we must develop clinical and policy solutions to protect vulnerable patients while preserving the elements of PAP integrial to safety and efficacy; this includes thorough preparation for the psychedelic experience.

Declaration of Conflicting Interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Daniel Rosenbaum has received salary support through a philanthropic grant from the Nikean Foundation, a nonprofit organization.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

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References

1. Reiff CM, Richman EE, Nemeroff CB, et al. Psychedelics and psychedelic-assisted psychotherapy. Am J Psychiatry. 2020;177(5):391–410. doi:10.1176/appi.ajp.2019.19010035
2. Yaden DB, Griffiths RR. The subjective effects of psychedelics are necessary for their enduring therapeutic effects. ACS Pharmacol Transl Sci. 2021;4(2):568–572. doi:10.1021/acsptsci.0c00194
3. Olson DE. The subjective effects of psychedelics may not be necessary for their enduring therapeutic effects. ACS Pharmacol Transl Sci. 2021;4(2):563–567. doi:10.1021/acsptsci.0c00192
4. Kangaslampi S. Association between mystical-type experiences under psychedelics and improvements in well-being or mental health – a comprehensive review of the evidence. J Psychedelic Stud. 2023;7(1):18–28. doi:10.1556/2054.2023.00243
5. Amsterdam JV, Opperhuizen A, Brink WVD. Harm potential of magic mushroom use: a review. Regul Toxicol Pharmacol. 2011;59(3):423–429. doi:10.1016/j.yrtph.2011.01.006
6. Zeifman RJ, Wagner AC, Monson CM, Carhart-Harris RL. How does psilocybin therapy work? An exploration of experiential avoidance as a putative mechanism of change. J Affect Disord. 2023;334:100–112. doi:10.1016/j.jad.2023.04.105
7. Back A, Bates M, Carlin S, Gukasyan N, Penn A, Sloshower J, & Van Derveer W. Professional practice guidelines for psychedelic assisted therapy. American Psychedelic Practitioners Association; 2022.
8. Mithoefer, M. A manual for MDMA-assisted psychotherapy in the treatment of posttraumatic stress disorder. 2016. Version 8: http://www.maps.org/research/mdma/mdma-research-timeline/4887-a-manual-for-mdmaassisted-psychotherapy-in-the-treatment-of-ptsd
9. Guss, J, Krause, R, & Sloshower, J. The Yale manual for psilocybin-assisted therapy of depression (using acceptance and commitment therapy as a therapeutic frame). PsyArXiv. 2020 [cited 2023 Oct 10]. II.16 (p.42). https://osf.io/u6v9y
10. Rochester J, Vallely A, Grof P, Williams MT, Chang H, Caldwell K. Entheogens and psychedelics in Canada: proposal for a new paradigm. Can Psychol Psychol Can. 2022;63(3):413–430. doi:10.1037/cap0000285
11. Faden RR, Beauchamp TL. A history and theory of informed consent. New York: Oxford University Press; 1995.
12. Gopal AA, Cosgrove L, Shuv-Ami I, Wheeler EE, Yerganian MJ, Bursztajn HJ. Dynamic informed consent processes vital for treatment with antidepressants. Int J Law Psychiatry. 2012;35(5–6):392–397. doi:10.1016/j.ijlp.2012.09.006
13. Smith WR, Sisti D. Ethics and ego dissolution: the case of psilocybin. J Med Ethics. 2021;47(12):807–814. doi:10.1136/medethics-2020-106070
14. Jacobs E. Transformative experience and informed consent to psychedelic-assisted psychotherapy. Front Psychol. 2023;14:1108333. doi:10.3389/fpsyg.2023.1108333
15. Barrett FS, Bradstreet MP, Leoutsakos JMS, Johnson MW, Griffiths RR. The challenging experience questionnaire: characterization of challenging experiences with psilocybin mushrooms. J Psychopharmacol (Oxf). 2016;30(12):1279–1295. doi:10.1177/0269881116678781
16. Evans J, Luke D, Lutkajtis A, Michelle K, Murphy-Beiner A, Robinson O. Challenging psychedelic experiences project. 2023.
17. Johnstad PG. Day trip to hell: a mixed methods study of challenging psychedelic experiences. J Psychedelic Stud. 2021;5(2):114–127. doi:10.1556/2054.2021.00155
18. Gashi L, Sandberg S, Pedersen W. Making "bad trips" good: how users of psychedelics narratively transform challenging trips into valuable experiences. Int J Drug Policy. 2021;87:102997. doi:10.1016/j.drugpo.2020.102997
19. Hartogsohn I. Set and setting, psychedelics and the placebo response: an extra-pharmacological perspective on

psychopharmacology. J Psychopharmacol (Oxf). 2016;30(12):1259–1267. doi:10.1177/0269881116677852

20. Doyle MA, Ling S, Lui LMW, et al. Hallucinogen persisting perceptual disorder: a scoping review covering frequency, risk factors, prevention, and treatment. Expert Opin Drug Saf. 2022;21(6):733–743. doi:10.1080/14740338.2022.2063273
21. Lindsay B. Footage of therapists spooning and pinning down patient in B.C. trial for MDMA therapy prompts review. *CBC News*, 29 March 2022. https://www.cbc.ca/news/canada/british-columbia/bc-mdma-therapy-videos-1.6400256
22. McNamee S, Devenot N, Buisson M. Studying harms is key to improving psychedelic-assisted therapy—participants call for changes to research landscape. JAMA Psychiatry. 2023;80(5):411. doi:10.1001/jamapsychiatry.2023.0099
23. Mackenzie C, Stoljar N. Relational autonomy: feminist perspectives on autonomy, agency, and the social self. New York: Oxford University Press; 1999.
24. Gaillard AS, Braun E, Vollmann J, Gather J, Scholten M. The content of psychiatric advance directives: a systematic review. Psychiatr Serv. 2023;74(1):44–55. doi:10.1176/appi.ps.202200002
25. Zohny H, King M. Respecting autonomy in altered states: navigating ethical quandaries in psychedelic therapy. 2021. https://blogs.bmj.com/medical-ethics/2021/12/22/respecting-autonomy-in-altered-states-navigating-ethical-quandaries-in-psychedelic-therapy/.
26. Devenot N, Tumilty E, Buisson M, McNamee S, Nickles D, Ross LK. A precautionary approach to touch in psychedelic-assisted therapy. 2022. https://blog.petrieflom.law.harvard.edu/2022/03/09/precautionary-approach-touch-in-psychedelic-assisted-therapy/.
27. Thal, S, Engel, LB, & Bright, SJ. Presence, trust, and empathy: preferred characteristics of psychedelic carers. J Humanist Psychol. 2022. doi:10.1177/00221678221081380
28. Hughson J-A, Woodward-Kron R, Parker A, et al. A review of approaches to improve participation of culturally and linguistically diverse populations in clinical trials. Trials. 2016;17(1):263. doi:10.1186/s13063-016-1384-3
29. Michaels TI, Purdon J, Collins A, Williams MT. Inclusion of people of color in psychedelic-assisted psychotherapy: a review of the literature. BMC Psychiatry. 2018;18(1):245. doi:10.1186/s12888-018-1824-6
30. Williams MT, Reed S, Aggarwal R. Culturally informed research design issues in a study for MDMA-assisted psychotherapy for posttraumatic stress disorder. J Psychedelic Stud. 2019;4(1):40–50. doi:10.1556/2054.2019.016