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Review

Ethics of Psychedelic Use in Psychiatry and Beyond—Drawing upon Legal, Social and Clinical Challenges

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Abstract: Background: Psychedelics are known for their powerful mental effects due to the activation of 5HT-2A receptors in the brain. During the 1950s and 1960s, research was conducted on these molecules until their criminalization. However, their clinical investigation as therapeutic tools for psychiatric disorders has revived the deontological ethics surrounding this subject. Questions arise as research on their therapeutic outcome becomes a reality. We aim to explore deontological ethics to understand the implications of psychedelics for the clinician, patient, and society. Results: A total of 42 articles were considered for this review. Methods: A methodological search of psychedelic studies from 2017 to 2022 was conducted in PubMed, Scopus, EBSCOhost, and ScienceDirect to address the deontological ethics of clinical psychedelic use. Conclusion: Psychedelics need to be culturally contextualized, epistemic harm minimized and represented to ensure informed consent. Open data and commissions are needed to ensure safe and equal distribution.

Keywords: ethics; psychedelic-assisted therapy; cultural; legislation; informed consent

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1. Introduction

In recent years, there has been a significant surge of interest in the use of psychedelics in clinical practice. This has been accompanied by a wave of new studies exploring their potential therapeutic applications [1]. However, it is important to note that this interest is not entirely novel, as research conducted in the 1950s already investigated the use of psychedelics in treating psychiatric disorders such as major depression, post-traumatic stress disorder, and anxiety. Currently, clinical trials in various phases (I, II, and III) are underway in countries including the United States, Canada, the United Kingdom, Switzerland, The Netherlands, and Israel, yielding promising results in several psychiatric pathologies [2]. While robust evidence for efficacy is still being established, preliminary data on psychedelic use suggest physiological safety and a low risk of dependence or misuse [3].

The increased prevalence of research on alternative molecules, such as psychedelics [4], stems partially from a dearth of new psychiatric interventions in the past decade. Conventional drugs like selective serotonin reuptake inhibitors (SSRIs) have exhibited high failure rates even when compared to placebo [5], leading to a search for novel treatment options. Furthermore, shortcomings in research on conventional drugs, including poor diagnostic category clarification, inflated baseline measurements, and inconsistent or unreliable assessments, have further fuelled the exploration for alternative interventions [6,7]. Psychedelic treatment stands apart from conventional psychopharmacological therapy due to the need for specialized care. Psychological support and/or psychotherapy are integral components of psychedelic treatment, shaping the therapeutic experience and contributing to its positive outcomes [8]. This support is crucial for patient safety during the altered state of consciousness induced by psychedelics [9].

Psychedelics belong to a class of serotonergic agonists with immediate psychoactive effects. The "typical" psychedelics, which include classic hallucinogens, are partial agonists

of the 5-HT2A serotonin receptors in the pre-frontal cortex [10]. Through their binding, they generate inositol triphosphate (IP3), leading to the release of intracellular calcium and increased glutamatergic transmission in afferent pyramidal neurons [11]. This amplifies the transmission of sensory information and induces perceptual disturbances. Table 1 presents the main psychedelics available and their origins.

Table 1. Typical psychedelics and their origins [10,12].

	Natural Origin
LSD (lysergic acid diethylamide)	Ergot fungi
Psilocybin	Psilocybe spp. mushrooms
Mescaline	Peyote; San Pedro Cactus
DMT (N,N-dimethyltryptamine)	Ayahuasca (mixture of many plants)

Additionally, there is another class referred to as "atypical psychedelics" that produce psychedelic effects but do not fit neatly into the classic hallucinogen category. These induce dissociative and/or empathogenic effects, altering an individual's perception of reality and increasing feelings of connection and empathy. This category includes ketamine, methylenedioxymethamphetamine (MDMA), and 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT) [13]. Ketamine is primarily used as an anesthetic due to its non-competitive antagonism on ionotropic glutamate receptors of the NMDA type [11]. It has also shown promise in the treatment of treatment-resistant depression, with esketamine nasal spray and EMA for use in conjunction with oral antidepressants being approved by the FDA [14,15]. MDMA, on the other hand, acts as an empathogen by reversing the action of amine transporters and releasing biogenic amines [16]. While the addiction risk associated with these substances is still debated, there is currently no evidence of dependence or addiction to either ketamine or esketamine [12]. Table 2 provides an overview of the role of both typical and atypical psychedelics in the treatment of key psychiatric disorders. These substances have shown promise in clinical trials for conditions such as major depression, post-traumatic stress disorder (PTSD), anxiety disorders, and substance use disorders. However, further research is needed to establish their efficacy and safety profiles.

Table 2. Psychedelics and therapies under research.

	Depressive Disorders	**Anxiety Disorders**	**Substance Use Disorder**	**Other Disorders**
LSD	_____	Anxiety AALTD	Opioid Use Disorder Alcohol Use Disorder	Cluster Headache
Psilocybin	DRLTC MDD TRD [a]	ARLTC	Nicotine Use Disorder Alcohol Use Disorder	Eating Disorders
DMT	TRD	_____	_____	_____
Ketamine	MDD	_____	Opioid Use Disorder Alcohol Use Disorder [b]	_____
MDMA	_____	_____	Alcohol Use Disorder	PTSD [c]

[a] Phase IIb concluded. [b] Phase IIa and Phase IIb concluded. Preparing an Oxford Health NHS Foundation Trust-funded Phase III trial. [c] Phase II and Phase IIIa concluded. Phase IIIb is concluded and under review. **Abbreviations: AALTD**—anxiety associated with life-threatening diseases; **DRLTC**—depression related to life-threatening cancer; **MDD**—major depression disorder; **TRD**—treatment-resistant depression; **ARLTC**—anxiety related to life-threatening cancer; **PTSD**—post-traumatic stress disorder. Sources: LSD [17,18]; Psilocybin [3,8,19–21]; MDMA [22].

Bearing in mind that (1) some of these psychedelics are naturally occurring agents that are (or grow in places where they are) ecologically endangered, as well as an important part of Native American and Amazonian cultures, there are risks of exploiting endangered plants or fungi, furthering their decline or disrupting their fragile ecosystem (threatening long-term availability and sustainability) and the risk of cultural appropriation diminishing the heritage and traditions of these communities without proper consent, recognition, and/or compensation of indigenous communities; (2) that changes in cognition, perception, and connection that occur in psychedelic-induced states pose specific challenges to the therapeutic relationship; (3) that psychedelics are substances charged with complex political, cultural, and legal meanings risks biasing stakeholders into positive or negative decision-making for reasons beyond actual research inputs, our systematic review aims to provide a contemporary one-health approach to the cultural, political, social, and ecological dimensions of these ethical issues. We will discuss psychedelics' unique context, such as the intellectual appropriation of Indigenous cultures and the risk of ecological repercussions. We will explore ethical issues that could arise from the intricacies of written informed consent, questions raised by spiritual or religious occurrences during therapy, and their approval for use in vulnerable populations such as mental disorder patients. We'll also discuss the risk of biased research and the hazards of overenthusiasm in rapid media acceptance and marketing campaigns. Lastly, we intend to discuss the convoluted legal framework needed for the use of psychedelics in clinical practice after their approval.

2. Methods

This integrative review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) recommendations as reporting guidelines [23]. The search strategy aimed to identify relevant studies and employed a combination of electronic database searches, citation tracking, and reference checking. The following databases were searched: PubMed Central, ScienceDirect, EBSCOhost, and SCOPUS. The search was conducted in November 2022. Table 3 presents the inclusion criteria. The reviewed papers were written over the last five years (2017–2022) and were written in English. A total of 55,703 studies were initially identified through the search. Titles and abstracts were reviewed using Mendeley, resulting in the exclusion of 52,373 records that did not meet the inclusion and exclusion criteria. After screening, 42 papers were included for thematic analysis. This allowed us to identify 6 main themes, which are presented in Figure 1. Appendix A details how the thematic analysis is distributed across our papers.

Table 3. Inclusion criteria.

Inclusion Criteria
1. Original peer-reviewed studies, theses/dissertations, reviews, follow-up studies, commentaries, opinion pieces, conference abstracts, study protocols of clinical trials
2. Study designs including quantitative, qualitative, mixed-methods, case reports, case series
3. Eligible psychedelic compounds: psilocybin, LSD, MDMA, ketamine, and ayahuasca
4. Discussion of ethical, legal, and clinical themes

Data extraction was conducted on 11 November 2022 and managed using Mendeley. Table 4 presents general information about the included studies, including bibliographic details, country, design, and purpose (shown at the end of our document). A synthesis of findings from selected publications was performed to identify themes and subthemes. Thematic analysis was conducted by identifying pertinent subjects across the articles and grouping related topics into larger categories. The themes and subthemes represented in each research study are summarized in a separate table. Given the diverse aims, approaches, and results of the included studies, a qualitative methodology was used to summarize the findings. A meta-analysis was not possible due to the heterogeneity of the studies. The quality of the research evidence from the selected publications was evaluated using

Hawker's tool [24], provided in Appendix C. This tool consists of nine questions, with answer choices of "good", "fair", "poor", or "very poor". Each research project was assigned a numerical score ranging from 9 (very poor) to 36 (good) based on the responses. Overall quality grades were established as follows: high quality (A) for scores of 30–36, medium quality (B) for scores of 24–29, and low quality (C) for scores of 9–23. A quality assessment of the included studies is provided in Appendix B. All included studies received an A or B grade with a numerical rating of 24–35.

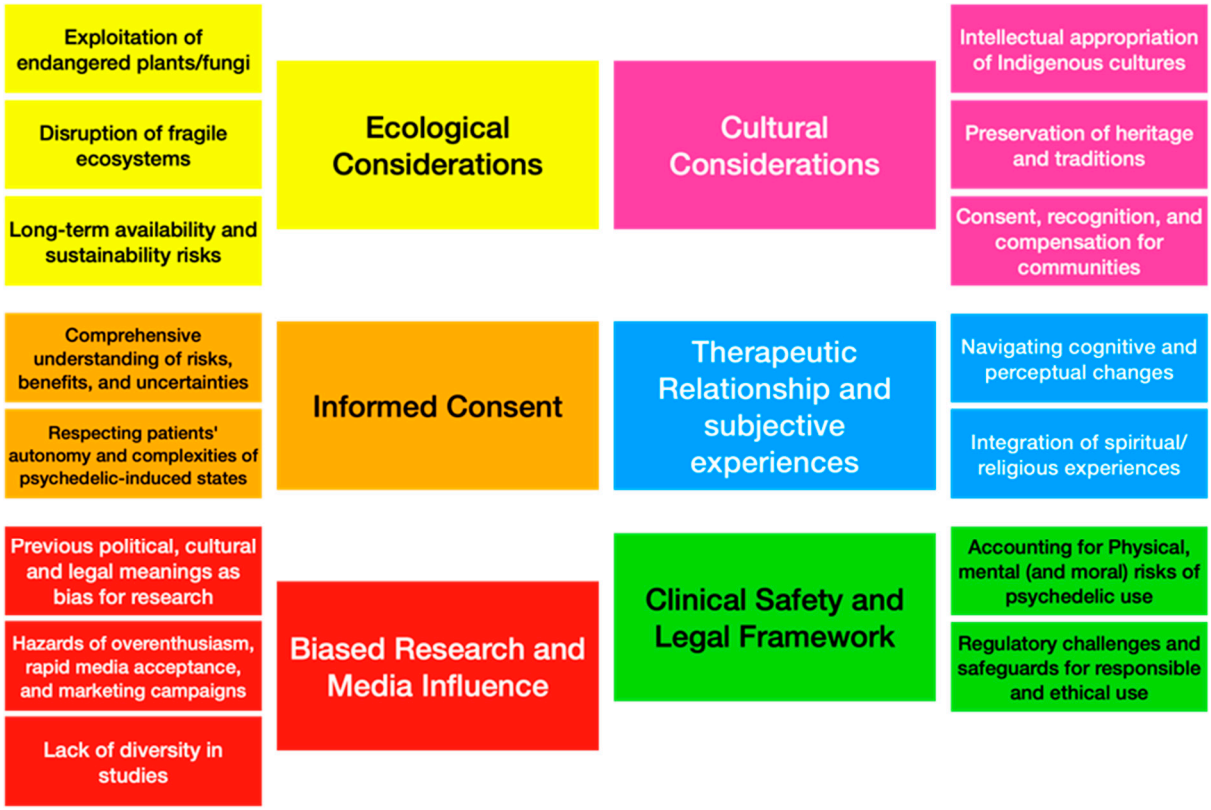

Figure 1. Thematic Analysis.

Table 4. Studies included.

Main Author, Year	Country	Study Design	Purpose of Study
(Miceli McMillan, 2022)	Australia	Essay	Cultural impact on and injustice towards Indigenous communities due to the scientific use of psychedelics.
(Cusimano, 2022)	USA	Research Article	Discussion with students about problems and solutions related to psychedelic therapy.
(Greif and Šurkala, 2020)	Slovak Republic	Perspective	Initial experiments and reflection about psychedelics' real therapeutic effect.
(Plesa and Petranker, 2022)	Canada	Research Article	Neo-liberalism and the risks of psychedelics in the self-help industry.
(Rucker and Young, 2021)	United Kingdom	Perspective	Discussion of the acceleration of studies on psychedelics and their risks.
(Johnson, 2021)	USA	Opinion	Beliefs and religion during therapy and the therapist's own beliefs.
(Bodnár and Kakuk, 2019)	Hungary	Review	Ethics of clinical research with LSD using the 7 dimensions of E. J. Emanuel.

Table 4. *Cont.*

Main Author, Year	Country	Study Design	Purpose of Study
(Miceli McMillan, 2020)	Australia	Essay	Hedonistic concepts used in psychedelic therapy.
(Langlitz et al., 2021)	USA, Canada, Switzerland, Germany	Perspective	Whether psychedelics can help users connect with their ideals and support moral–political ideas.
(Smith and Appelbaum, 2022)	USA	Review	Recommendations for solutions to novel problems concerning psychedelics.
(Letheby, 2022)	Australia, Canada	Review	The establishment of emerging lines of research at the intersection of philosophy and psychedelic science.
(Hauskeller et al., 2022)	United Kingdom	Research Article	The study of psychedelics with dualistic concepts used in colonial and decolonial thought.
(Stauffer et al., 2022)	USA	Research Article	The participation of transgender and gender-diverse people in PTSD research and assessment for their openness to MDMA-assisted psychotherapy.
(Miceli McMillan, 2021)	Australia	Research Article	A bioethical reflection about re-medicalization of psychedelics.
(Mintz et al., 2022)	USA, United Kingdom	Perspective	Encouragement for further research and debate to make psychedelic research and therapies accessible to members of disability communities.
(Kious et al., 2022)	USA	Perspective	If psychedelics can affect investigators' enthusiasm, raising concerns about bias and scientific integrity.
(Petranker et al., 2020)	Canada	Perspective	The importance of open science on psychedelic research.
(Pilecki et al., 2021)	USA	Opinion	How therapists can mitigate risks and practice within legal and ethical boundaries when incorporating psychedelics into traditional psychotherapy.
(van Amsterdam et al., 2021)	The Netherlands	Research Article	Hypothetical Dutch reform legislation to create a rational MDMA policy.
(Schleim, 2022)	The Netherlands	Opinion	Discussion on context-dependency of placebo effects and moral psychopharmacology.
(Williams et al., 2021)	Australia	Perspective	Discussion of potential psychedelic obstacles to community clinics among a group of clinicians and researchers.
(Page, L.A. et al., 2021)	United Kingdom	Brief Report	The attitudes and knowledge of NHS psychiatrists on psychedelic-assisted psychotherapy.
(Marcus, 2022)	USA	Research Article	Ethical tensions between curanderos, mental health practitioners, and ayahuasca retreat centers.
(Gerber et al., 2021)	Brazil, Mexico, Switzerland, USA	Opinion	How Indigenous communities are currently unable to claim their rights to traditional medicines, despite international treaties.
(Mocanu et al., 2022)	Canada	Essay	A demonstration that expanding access to psychedelics requires consideration of a range of factors.
(Askew and Williams, 2021)	United Kingdom	Research Article	Critical discourse examining how substances can be used for self-improvement.
(Thal et al., 2021)	Australia, Germany	Review	A description of the current conditions and theoretical knowledge for substance-assisted psychotherapy, including ethics and spiritual emphasis, methods, models, and concepts of psychological mechanisms of action.

Table 4. *Cont.*

Main Author, Year	Country	Study Design	Purpose of Study
(Yaden et al., 2022)	USA	Opinion	How psychedelic research should focus on integrating medications into the standard of care rather than recreating ethical and socio-political problems.
(Campbell and Williams, 2021)	USA, Canada	Perspective	A discussion of whether psychiatry should allow patients' preferences to guide policy and law regarding psychedelics.
(Smith and Appelbaum, 2021)	USA	Opinion	A discussion about Oregon and California's different approaches to legalization, with cautionary precedents.
(Mathai et al., 2022)	USA	Research Article	Informed consent processes for ketamine therapy clinicians to identify the potential for growth.
(Žuljević et al., 2022)	Croatia	Research Article	Psychometric properties of the Attitudes on Psychedelics Questionnaire in a sample of the Croatian general population.
(Peterson et al., 2019)	USA, Argentina, Canada	Opinion	Ethical analysis of psychedelic research involving consciousness patients.
(Levin et al., 2022)	USA	Research Article	Examining whether psychiatrists' perceptions of four psychoactive drugs differ from schedules.
(Corrigan et al., 2022)	Ireland	Research Article	Analyzing mental health service users' attitudes to psychedelics and psilocybin therapy.
(Michaels et al., 2018)	USA	Review	Examining ethno-racial differences in inclusion and recruitment of people of color in psychedelic clinical trials.
(Phelps, 2017)	USA	Research Article	To review and compile psychedelic therapist competencies derived from the psychedelic literature.
(Smith and Sisti, 2021)	USA	Research Article	To show that psychedelics pose novel risks and require enhanced informed consent, leading to ethical considerations as they move into mainstream clinical psychiatry.
(Brennan et al., 2021)	USA	Research Article	An interview with 23 psychedelic clinicians about nonsexual touch, sexual boundary-setting, and experiences while navigating multiple relationships in their work.
(Dupuis, 2021)	France	Research Article	An argument on how hyper suggestibility is the main factor in making psychedelics powerful for belief transmission, producing doubt, ambivalence, and reflexivity.
(Eleftheriou and Thomas, 2021)	United Kingdom	Review	An explanation of how mindfulness-based interventions and psychedelic therapy have been found to have synergistic effects, but replication is needed to fully understand the effects of set and setting.
(Kuypers et al., 2019)	The Netherlands, United Kingdom, Denmark, USA, Italy	Opinion	To answer questions and provide guidelines for research on microdosing.

3. Discussion of the Analysis

3.1. Ecological and Cultural Considerations

The eventual therapeutic use of psychedelics raises several social issues, including ecological concerns associated with their sustainability and the impact on natural organisms that are already endangered. The growing industry around psychedelic science poses risks to the availability of naturally occurring psychedelics, leading to a reduction in their availability for traditional and Indigenous healing practices (biopiracy) [25]. The synthesis

of active compounds from natural organisms could help mitigate this ecological issue, but concerns exist regarding the therapeutic equivalence of synthetic forms and the potential loss of therapeutic properties without the ritualistic process. More studies are needed to address these ecological questions and ensure the sustainability of psychedelics in therapeutic contexts [25,26].

The cultural contextualization of psychedelics as a form of colonialist appropriation of Indigenous knowledge is a significant social issue. The Western approach to psychedelics risks reframing and disturbing the integrity and stability of diverse and unique cultures that have used psychedelics in the past. The paradigmatic case is Maria Sabina, who shared her knowledge of the Mazatec community with one "white man" [27], which led to her arrest, her house being burned down, and the loss of her social role as a healer. Criticisms within Western culture support the idea that it might be wrong to patent this mode of intervention as these are ritualistic approaches whose appropriation was never consented to by Indigenous communities [28]. The appropriation of Indigenous practices without proper consent has been criticized within Western culture. According to the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), prior consent and fair sharing of profits with Indigenous communities should be ensured for all forms of bioprospecting [29]. It is suggested that Indigenous people act as key consulting stakeholders to guide therapies alongside scientists and be included in clinical trials to respect and honor Indigenous knowledge and traditions [27,28].

3.2. Informed Consent

In altered states of consciousness, patients become more vulnerable and may be unable to protect their own interests. For instance, psychedelics are empathogens and increase suggestibility/susceptibility [30], resulting in a vulnerable state of mind [31] that makes patients susceptible to abuse from their treatment providers (nurses, psychiatrists, therapists) as after intake they might be less likely to refuse physical touch and sexual advances and engage in sexual behaviors that they later (in a clearheaded state) consider forms of abuse [32–34]. Such vulnerability exposes them to potential abuse from therapists, doctors, or practitioners. Informed consent (IC) in psychedelic research becomes a critical consideration in addressing these risks. Ensuring comprehensive and personalized IC procedures is crucial for addressing the particular risks associated with psychedelic therapy and safeguarding the well-being and autonomy of patients. IC in the field of psychedelic treatment is an area for development, as evidenced by the fact that 23 clinics approved by the American Society of Ketamine Physicians, Psychotherapists, and Practitioners (ASKP3), have concluded that most IC processes need improvement [35]. See Table 5 for a resume of the requirements of informed consent psychedelic interventions.

Table 5. Possible requirements of Informed Consent in Psychedelic treatment.

Should be obtained from every patient undergoing psychedelic therapy, regardless of prior experience with psychedelics [36].
Should clarify the realistic expectations of the intervention, distinguishing them from media-generated unrealistic expectations. IC should also cover evidence-based effects for each medical situation [33].
Must encompass all types of decision-making following psychedelic intake, including physical boundaries between patient and therapist, the risk of self-harm, violent events, and property destruction [31,34,37–39].
Needs to include potential long-term side effects [31], which might include changes in moral, philosophical, political, and religious beliefs that can result from psychedelic therapy [30,38,39].
Should account for potential cultural differences between the patient and therapist to avoid misunderstandings during the therapy session [30,34].
Should include provisions for the patient's decision to leave the session during the altered hallucinogenic state, allowing researchers and clinicians to respect the patient's autonomy [36].
Could include surrogate decision-making in case of changes that make the patient unable to decide under psychedelic effects [36].
Should be tailored for patients with physical and mental impairments, considering the involvement of caregivers as decision-makers [40].

3.3. Biased Research and Media Influence

Media plays a role in shaping public perception and expectations surrounding psychedelic interventions. Unrealistic expectations and non-evidence-based illusions about their therapeutic value can be generated, concealing risks and harms. There is pressure on mental health services and research to hasten trials and therapeutic formation due to social needs and public demand [41]. Over-crediting psychedelic interventions by generating unrealistic expectations and non-evidence-based illusions would damage their actual therapeutic value. Risks and harms appear to be concealed, and pressure is put on mental health services to make them available and on researchers to hasten their trials [41]. It is important to acknowledge the lack of safety and effectiveness guarantees in current interventions with psychedelics, as well as the potential for illegal practices. Moreover, the induced altered state could enable (even healthy) subjects to fail to protect their rights, e.g., be lured into cults, become vulnerable to sexual harassment [32,33], and risk other forms of abuse [30]. The medical community must adhere to ethical principles, ensuring that interventions are evidence-based and provided at reasonable prices. Offering interventions without therapeutic benefit and charging for them is unethical and violates patient rights, as stated in the Helsinki Declaration [42].

Therapists' own subjective experiences with psychedelics also raise concerns [43]. Some therapists openly admit to having previously used psychedelics, which is seen as a conflict of interest and bias by lawyers and regulatory bodies [44]. They cite the example of Timothy Leary (a researcher of psychotropic drugs that actively promoted their recreational use, leaving aside the scientific method), demonstrating that this field is not different from others, where biased results of clinical research could mean that scientific methodologies are abandoned in favour of personal beliefs. Indeed, his beliefs attracted controversy both for institutions (Harvard sacked Leary from his position) [45] and key stakeholders (peer pressure on avoiding stereotypes in the research field) [43]. While some argue that previously altered states of mind are essential for empathizing with patients [19]; [20,46], the requirement for therapists to take psychedelics before performing interventions lacks evidence [47]. Ethically, it is rational for researchers and therapists to disclose their previous psychedelic use [39], and including naïve researchers in investigational teams and clinical interventions can help control bias and reduce conflicts of interest [43].

The need for enhanced research to address biases and combat non-evidence-based media coverage is highlighted [48]. This is crucial for promoting accurate and reliable information in the field. To mitigate biases and confounding factors, the authors propose several types of research protocols. These include pre-registration, double- and triple-blind protocols, open materials and open data, constraints on generality, replication, and adversarial collaboration [41,48–51]. These protocols aim to enhance the rigor and validity of psychedelic research. Implementing robust research protocols would enable researchers and practitioners to better understand the mechanisms of action underlying psychedelic therapy. This understanding is essential for optimizing dosage, selecting the most effective compounds, and guiding clinical practice [41,52,53]. The insights gained from enhanced research should be consolidated into official, nationwide multidisciplinary norms, which would provide guidelines for therapists, physicians, researchers, and regulators involved in psychedelic therapy [34,36,39,54]. They would serve as a reference for ethical practice and standardize approaches within the field. Existing ethical codes, such as the MAPS Code of Ethics and the Code of Ethics for Spiritual Guides from the Council on Spiritual Practices, can serve as examples of guidelines for practitioners to follow during psychedelic therapy sessions [39,55,56]. These codes ensure ethical conduct and safeguard the well-being of patients.

Research in the field of psychedelics often relies on selected samples that may not be representative of those who will benefit from the interventions. Disproportionate representation is observed in the racial composition of research participants, with white individuals overrepresented, comprising most participants in psychedelic research [57]. Certain groups, such as transgender and gender-diverse individuals, are seldom included in studies, leading to a lack of knowledge about the efficacy and safety of psychedelic

therapy for these populations [58,59]. Indigenous people and individuals with physical disabilities are also underrepresented in psychedelic research. While Indigenous people constitute a significant percentage of the population, they make up only a small proportion (4.6%) of research participants [57]. Similarly, people with physical disabilities are rarely included [40]. All these marginalized groups share potential contexts for trauma, including experiences of discrimination, and could benefit from clinical research in this field [57]. This lack of diversity limits the generalizability of findings and raises concerns about equitable access to psychedelic therapy. Efforts should be made to increase the representation of underrepresented groups in future clinical trials. Examples such as a Phase IIIb clinical trial on MDMA for PTSD treatment, which implicitly included non-white individuals, can serve as models for inclusivity [60].

3.4. Therapeutic Relationship and Subjective Experiences

Ethical debates also arise on the disintegration of reality perception and hallucinations experienced during psychedelic interventions, which some argue distance patients from reality [61–64]. However, counterarguments challenge the notion of a singular true reality and highlight the potentially traumatic nature of patients' pre-treatment reality, particularly for those with major depression and suicidal ideation [31,63]. The brief hallucinatory state allows individuals to reconsider their experiences in a natural state, leading to the emergence of new elements and a fresh perspective on personal problems [37]. This highlights the importance of well-trained therapists to guide patients through these experiences effectively [39,53,65].

Research demonstrates that psychedelic treatment can be one of the most meaningful experiences in some patients' lives [18,66–71]. Spiritual and religious experiences may occur during psychedelic interventions, presenting a challenge for untrained medical professionals and therapists. Inadequate handling of these elements could lead to the initiation of careless meta-religious beliefs or the disregard of patients' newly formed beliefs [38,69,72–74]. To address this, it is suggested that the session room avoids religious or non-religious iconography and suggestive artifices [38], employing training that focuses on aesthetics and philosophical questions expressed by the patient [39]. A multidisciplinary team, including anthropologists, philologists, and sociologists [30], can help address the complexity of the psychedelic session [33].

Another ethical issue revolves around the concept of moral enhancement through psychedelics [75]. Ethicists are concerned about the subjective experiences induced by psychedelics, which may lead to changes in values and beliefs, potentially impacting patients' relationships with others [30]. While only moral decision-making paradigms have been studied in pharmacological experiments [75], the intention to enhance moral competence through psychedelics remains unclear. Enhancers are classified into healing, transformative, and productivity discourses, but the aim is to dispel the stigma surrounding enhancement [76]. Psychedelics are viewed as substances used to improve mental health issues, spirituality, and well-being, rather than as moral enhancers. Further exploration and understanding of the effects of psychedelics on moral capacities are necessary.

3.5. Safety and Legal Framework

The risks associated with psychedelic therapy encompass both physical and mental effects, including cardiovascular and systemic risks, as well as risks related to hallucinations, reality perception, and trauma [54]. Rebound depressive and anxious symptoms, acute stress reactions, and psychosis are among the reported risks [17,21,36,54,77,78]. Indeed, prolonged psychosis is expected in 5 out of 5000 general patients, 37 out of 4300 psychiatric patients, and 4 out of 1000 patients with a personal or family history of psychotic disorder when taking psilocybin [37] and has also been observed in those using other classic psychedelics [36,54]. Certain interactions with other drugs, particularly MAO inhibitors, can also pose risks [9,79]. These risks determine the exclusion of individuals with psychosis from most clinical trials.

This is particularly problematic as the growing industry of psychedelics is not limited to therapeutic applications but also includes non-medical forms of intervention where no psychiatric history might be available. Some self-help ideologies associated with psychedelic use may lead to moral harassment, where patients feel shamed or guilty for their mental health conditions and believe they should recover alone [48,80]. These non-medical interventions, often provided in private centers with non-clinical therapists, lack evidence of effectiveness and safety. The efficacy of psychedelics itself is not fully understood, and their application in clinical trials varies, posing challenges to fidelity and generalizability [34]. Safety concerns also exist, as studies conducted under controlled settings may not fully account for risks that can arise in clinical settings, such as concomitant use of antidepressants, personal and family history of mental illness, and the patient's present mindset, which may increase the risk of adverse experiences such as a "bad trip" or other forms of trauma [33,65]. Table 6 summarizes some of the clinical and ethical safeguards that should be taken into account.

Table 6. Clinical Considerations.

Clinical Consideration	Description
Need for Evidence and Training [48,54,81]	Prioritize evidence of efficacy, effectivity, and the training of mental health professionals in psychedelic therapy.
	Avoid hasty preparation of therapists to prevent harm and ensure safe settings.
	Provide diverse training to therapists and prescribers accredited by national and regulated entities.
Importance of Setting [40,54]	Create a calm, natural-like, and personalized setting in psychedelic therapy.
	Enhance therapeutic effects and reduce adverse events through an appropriate setting.
	Ensure inclusivity for individuals with physical disabilities, enabling equal access to treatment.
Accessibility and Affordability [33,54,82–84]	Address questions of accessibility, overall price, and co-payment in psychedelic therapy.
	Consider the limited resources of patients impacted by their symptoms.
	Ensure equitable access to treatment, particularly for individuals with chronic psychiatric disorders, amid concerns about a for-profit industry.
Real-Life Practice vs. Research [54,85]	Recognize potential differences between research conducted in artificial settings and real-life clinical practice.
	Overcome challenges in patient selection, misdiagnosis, exclusion of at-risk individuals, and off-label use of psychedelics in clinical practice.
	Conduct controlled and comprehensive evaluations of diagnosis by clinicians before implementing psychedelic interventions to ensure patient safety and treatment benefits.

Psychedelics are currently considered illegal substances globally, despite recent evidence of their therapeutic benefits [86] and studies indicating openness towards psilocybin therapy [87] with 72% of people with mental disorders considering therapeutic psilocybin research important to continue and 54% willing to try the therapy if prescribed. Indeed, psychiatrists have raised concerns about other drug classes, such as benzodiazepines, which are legal but subject to questionable regulation [88,89]. Procedures to change the legal status of psychedelics involve two options: legalization [48] or decriminalization [48]. Legalization would involve regulating psychedelics and establishing a regulated market, while decriminalization would reduce penalties, encourage treatment for abuse, and support harm reduction. Both approaches have pros and cons, with legalization potentially sending the wrong message [90] and putting research and medical use at risk [41], while decriminalization may reduce stigma but still limit access to specific circumstances under medical and psychological supervision [34,48]. Oregon in the USA has decriminalized psilocybin for clinical interventions, establishing the Oregon Health Authority to oversee the process [90]. California has legalized the possession, personal use, and non-profit sharing of psychedelics for adults [90]. These approaches demonstrate different levels of regulation and conservatism, considering the ongoing research and lack of formal approval for psychedelic therapy [41,90]. Portugal's decriminalization of drugs in 2001 provides an example of both positive and negative outcomes. Drug-related casualties and HIV infections among drug users decreased significantly [91], and the number of people seeking treatment for

drug addiction doubled [91]. However, Portugal has also seen an increase in hospitalizations for psychotic disorders and cannabis-use disorder [92].

Some argue for specific regulation of psychedelics for research and treatment purposes [34,93,94]. This could involve creating institutions or "trip houses" that develop programs for patients under medical supervision [95]. A Dutch policymaking group suggested MDMA policies encompassing various regulation issues and monitoring aspects related to prevalence, health, criminality, and financial costs and benefits [96]. In addition to legal status, commercialization is an important matter to discuss. Patenting psychedelics is an ethical concern, as future marketing would reduce availability to specific communities (e.g., ayahuasca in Indigenous cultures) due to costs and other restrictions [28,97]. Patenting psychedelics raises ethical concerns as it can reduce availability to specific communities and introduce biases and conflicts of interest [48]. Patenting therapeutic procedures and protocols derived from Indigenous rituals is seen as ethically wrong as it might be a form of plagiarism [34,98,99] as well as contradicting communitarian social values [48,76]. Indeed, psychedelic use in Western society seems fuelled not by communitarian values but by neoliberal ideologies that wish for "individual freedom" to use psychedelics [100,101], which in its full-sized version was coined "McPsychedelics" [48,85]. There is an argument for national or regional governments to be responsible for prevention policy, harm reduction, and health education, and the Attitude on Psychedelics Questionnaire (APQ) has been suggested as a good tool to evaluate the general population's knowledge about psychedelics and opinions on their legal status and policies [102].

4. Conclusions

The use of psychedelics has raised significant ethical, social, and clinical challenges. First, ecological issues, such as the availability of naturally occurring psychedelics or the potential loss of therapeutic properties without the ritualistic process. Second, cultural issues emphasizing the risk of colonialist appropriation of Indigenous knowledge and the importance of respecting and including Indigenous communities in the development and practice of psychedelic therapy. Third, there are several issues regarding informed consent within the vulnerabilities and risks associated with altered states of consciousness induced by psychedelics. Comprehensive and personalized informed consent procedures seem necessary to safeguard the autonomy and well-being of patients. Fourth, media influence is presently shaping public perception and expectations of psychedelic therapy; therefore, enhanced research protocols and combating non-evidence-based media coverage are essential to promote accurate information. Fifth, training seems necessary and well-trained therapists are necessary to guide patients through altered states of consciousness and address the potential emergence of spiritual and religious experiences. These, together with short-term and long-term physical, mental, and moral effects, raise safety concerns and demand strong legal frameworks. Sixth, while still illegal drugs, the legal status of psychedelics and the potential for commercialization raise ethical concerns that require thoughtful regulation and consideration of access and availability. Overall, addressing these considerations in psychedelic therapy is crucial to ensure evidence-based practice, ethical conduct, patient safety, and equitable access to treatment. Continued research, training, and collaboration among diverse stakeholders are necessary to navigate these complex social, cultural, and ethical dimensions of psychedelic therapy effectively.

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Appendix A. Thematic Analysis

x—content discussed in this study.

Theme	Ecological Considerations		Informed Consent		Biased Research and Media Influence				Cultural Considerations			Therapeutic Relation and Subjective Experience		Clinical Safety and Legal Framework	
Sub-Theme	**Exploitation of Endangered Plants**	**Disruption of Fragile Ecosystems**	**Long-Term Availability and Sustainability**	**Understanding Risks, Benefits, and Uncertainties**	**Respecting Patients Autonomy**	**Previous Political, Cultural, and Legal Meanings Impact on Research**	**Hazards of Overenthusiasm, Rapid Media Acceptance, and Marketing Campaigns**	**Lack of Diversity in Studies**	**Intellectual Appropriation**	**Preservation of Heritages and Traditions**	**Consent, Recognition, and Compensation of Communities**	**Navigating Cognitive and Perceptual Changes**	**Integration of Spiritual and Religious Experiences**	**Accounting for Physical, Mental, and Moral Risks of Use**	**Regulatory Challenges and Safeguards for Responsible and Ethical Use**
(Miceli McMillan, 2022)	x	x	x						x	x	x				
(Cusimano, 2022)															x
(Greif and Šurkala, 2020)				x			x								x
(Plesa and Petranker, 2022)									x	x					x
(Rucker and Young, 2021)	x			x					x	x	x				
(Johnson, 2020)				x									x	x	
(Bodnár and Kakuk, 2019)				x	x								x	x	
(Miceli McMillan, 2020)													x	x	
(Langlitz et al., 2021)	x			x	x				x					x	x
(Smith and Appelbaum, 2022)						x	x	x						x	x
(Letheby, 2022)				x	x								x		
(Hauskeller et al., 2022)									x	x	x				

Theme	Ecological Considerations		Informed Consent		Biased Research and Media Influence			Cultural Considerations				Therapeutic Relation and Subjective Experience		Clinical Safety and Legal Framework	
Sub-Theme	**Exploitation of Endangered Plants**	**Disruption of Fragile Ecosystems**	**Long-Term Availability and Sustainability**	**Understanding Risks, Benefits, and Uncertainties**	**Respecting Patients Autonomy**	**Previous Political, Cultural, and Legal Meanings Impact on Research**	**Hazards of Overenthusiasm, Rapid Media Acceptance, and Marketing Campaigns**	**Lack of Diversity in Studies**	**Intellectual Appropriation**	**Preservation of Heritages and Traditions**	**Consent, Recognition, and Compensation of Communities**	**Navigating Cognitive and Perceptual Changes**	**Integration of Spiritual and Religious Experiences**	**Accounting for Physical, Mental, and Moral Risks of Use**	**Regulatory Challenges and Safeguards for Responsible and Ethical Use**
(Stauffer et al., 2022)								x							
(Miceli McMillan, 2021)									x	x					
(Mintz et al., 2022)				x	x	x	x								
(Kious et al., 2022)				x		x						x			
(Petranker et al., 2020)						x		x							
(Pilecki et al., 2021)						x	x	x							
(van Amsterdam et al., 2021)															X
(Schleim, 2022)				X	X									X	
(Williams et al., 2021)							X					X	X	X	
(Page L. A. et al., 2021)														X	
(Marcus, 2022)				X					X	X	X	X		X	
(Gerber et al., 2021)									X	X	X				
(Mocanu et al., 2022)															X
(Askew and Williams, 2021)					X									X	

Theme	Ecological Considerations		Informed Consent		Biased Research and Media Influence			Cultural Considerations				Therapeutic Relation and Subjective Experience		Clinical Safety and Legal Framework	
Sub-Theme	**Exploitation of Endangered Plants**	**Disruption of Fragile Ecosystems**	**Long-Term Availability and Sustainability**	**Understanding Risks, Benefits, and Uncertainties**	**Respecting Patients Autonomy**	**Previous Political, Cultural, and Legal Meanings Impact on Research**	**Hazards of Overenthusiasm, Rapid Media Acceptance, and Marketing Campaigns**	**Lack of Diversity in Studies**	**Intellectual Appropriation**	**Preservation of Heritages and Traditions**	**Consent, Recognition, and Compensation of Communities**	**Navigating Cognitive and Perceptual Changes**	**Integration of Spiritual and Religious Experiences**	**Accounting for Physical, Mental, and Moral Risks of Use**	**Regulatory Challenges and Safeguards for Responsible and Ethical Use**
(Thal et al., 2021)				X	X							X	X		
(Yaden et al., 2020)										X	X				
(Campbell and Williams, 2021)								x							
(Smith and Appelbaum, 2021)											x				
(Mathai et al., 2022)				x	x										
(Žuljević et al., 2022)							x				x	x		x	
(Peterson et al., 2019)				x	x										
(Levin et al., 2022)				x			x					x			
(Corrigan et al., 2022)												x		x	x
(Michaels et al., 2018)								x							
(Phelps, 2017)				x									x	x	x
(Smith and Sisti, 2021)				x	x							x	x		
(Brennan et al., 2021)				x										x	
(Dupuis, 2021)									x	x	x				

Theme	Ecological Considerations		Informed Consent		Biased Research and Media Influence			Cultural Considerations				Therapeutic Relation and Subjective Experience		Clinical Safety and Legal Framework	
Sub-Theme	**Exploitation of Endangered Plants**	**Disruption of Fragile Ecosystems**	**Long-Term Availability and Sustainability**	**Understanding Risks, Benefits, and Uncertainties**	**Respecting Patients Autonomy**	**Previous Political, Cultural, and Legal Meanings Impact on Research**	**Hazards of Overenthusiasm, Rapid Media Acceptance, and Marketing Campaigns**	**Lack of Diversity in Studies**	**Intellectual Appropriation**	**Preservation of Heritages and Traditions**	**Consent, Recognition, and Compensation of Communities**	**Navigating Cognitive and Perceptual Changes**	**Integration of Spiritual and Religious Experiences**	**Accounting for Physical, Mental, and Moral Risks of Use**	**Regulatory Challenges and Safeguards for Responsible and Ethical Use**
(Eleftheriou and Thomas, 2021)				x								x	x		
(Kuypers et al., 2019)								x				x	x		

Appendix B. Classification of the Studies Included

References	Abstract/ Title	Introduction/Aims	Data Collection	Sampling	Analysis	Ethics/Bias	Results	Generability	Implications	Total	Grade
(Miceli McMillan, 2022)	4	4	1	1	3	4	3	2	3	25	B
(Cusimano, 2022)	4	4	4	3	3	4	3	3	4	32	A
(Greif and Šurkala, 2020)	3	4	1	1	3	4	4	2	3	25	B
(Plesa and Petranker, 2022)	4	4	2	2	3	4	3	3	4	29	B
(Rucker and Young, 2021)	3	3	1	1	3	4	3	2	4	24	B
(Johnson, 2020)	2	3	1	1	3	4	3	3	4	24	B
(Bodnár and Kakuk, 2019)	4	4	3	2	4	4	4	3	4	32	A
(Miceli McMillan, 2020)	4	4	1	1	3	4	3	2	3	25	B
(Langlitz et al., 2021)	4	3	1	1	3	4	3	3	4	26	B
(Smith and Appelbaum, 2022)	3	4	1	1	4	4	4	3	4	28	B
(Letheby, 2022)	4	4	1	1	3	4	4	3	4	28	B
(Hauskeller et al., 2022)	4	4	1	1	3	4	2	3	3	25	B
(Stauffer et al., 2022)	3	4	3	4	4	4	3	3	4	32	A
(Miceli McMillan, 2021)	4	4	2	1	2	4	3	3	4	27	B
(Mintz et al., 2022)	4	4	2	1	3	4	3	3	4	28	B
(Kious et al., 2022)	4	4	1	1	4	4	3	3	4	28	B
(Petranker et al., 2020)	4	4	2	1	3	4	3	3	4	28	B
(Pilecki et al., 2021)	4	4	2	1	3	4	3	3	4	28	B
(van Amsterdam et al., 2021)	4	4	4	3	4	4	4	4	4	35	A
(Schleim, 2022)	3	3	2	1	3	4	3	3	3	25	B
(Williams et al., 2021)	4	4	2	1	4	4	4	3	4	30	A
(Page L. A. et al., 2021)	4	4	3	2	3	4	3	3	4	30	A
(Marcus, 2022)	3	4	2	1	3	4	3	3	3	26	B
(Gerber et al., 2021)	3	4	2	1	3	4	2	3	4	26	B
(Mocanu et al., 2022)	4	4	2	1	3	4	3	3	4	28	B
(Askew and Williams, 2021)	4	4	4	3	4	4	4	3	4	34	A
(Thal et al., 2021)	4	4	2	1	4	4	3	3	4	29	B

References	Abstract/ Title	Introduction/Aims	Data Collection	Sampling	Analysis	Ethics/Bias	Results	Generability	Implications	Total	Grade
(Yaden et al., 2020)	3	3	1	1	4	4	3	2	3	24	B
(Campbell and Williams, 2021)	4	3	1	1	3	4	3	2	3	24	B
(Smith and Appelbaum, 2021)	4	4	2	1	3	4	3	2	3	26	B
(Mathai et al., 2022)	4	4	4	4	4	4	3	4	4	35	A
(Žuljević et al., 2022)	4	4	4	3	4	4	4	3	4	34	A
(Peterson et al., 2019)	4	4	3	2	3	4	3	3	4	34	A
(Levin et al., 2022)	4	4	4	4	4	4	4	3	4	30	A
(Corrigan et al., 2022)	4	4	3	3	4	4	3	3	4	35	A
(Michaels et al., 2018)	4	4	3	3	4	4	3	3	4	32	A
(Phelps, 2017)	4	4	2	1	4	4	3	3	4	32	A
(Smith and Sisti, 2021)	4	4	2	1	4	4	3	3	4	29	B
(Brennan et al., 2021)	4	4	4	3	3	4	4	3	4	29	B
(Dupuis, 2021)	4	4	3	1	3	4	3	3	4	33	A
(Eleftheriou and Thomas, 2021)	4	4	2	2	3	4	3	3	4	29	B
(Kuypers et al., 2019)	4	4	3	2	3	4	3	3	4	30	A

Appendix C. Hawker´s Tool for Studies Quality Appraisal

The nine questions in the tool are as follows:

1. Abstract and title: Did they provide a clear description of the study?	Good: structured abstract with full information and clear title
	Fair: abstract with most of the information.
	Poor: inadequate abstract.
	Very poor: no abstract.
2. Introduction and aims: Was there a good background section and clear statement of the aims of the research?	Good: full but concise background to discussion/study containing up-to-date literature review and highlighting gaps in knowledge; clear statement of aim AND objectives including research questions.
	Fair: some background and literature review; research questions outlined.
	Poor: some background but no aim/objectives/questions OR aims/objectives but inadequate background.
	Very poor: no mention of aims/objectives; no background or literature review.
3. Method and data: Are the methods appropriate and clearly explained?	Good: method is appropriate and described clearly (e.g., questionnaires included); clear details of the data collection and recording.
	Fair: method appropriate, description could be better; data described.
	Poor: questionable whether the method is appropriate; method described inadequately; little description of data.
	Very poor: no mention of method AND/OR method inappropriate AND/OR no details of data.

4. Sampling: Was the sampling strategy appropriate to address the aims?	Good: details (age/gender/race/context) of who was studied and how they were recruited and why this group was targeted; the sample size was justified for the study; response rates shown and explained.
	Fair: sample size justified; most information given but some missing.
	Poor: sampling mentioned but few descriptive details.
	Very poor: no details of the sample.
5. Data analysis: Was the description of the data analysis sufficiently rigorous?	Good: clear description of how the analysis was carried out. Qualitative studies: Description of how themes derived/respondent validation or triangulation. Quantitative studies: Reasons for tests selected hypothesis driven/numbers add up/statistical significance discussed.
	Fair: descriptive discussion of the analysis.
	Poor: minimal details about analysis.
	Very poor: no discussion of the analysis.
6. Ethics and bias: Have ethical issues been addressed and has necessary ethical approval been gained? Has the relationship between researchers and participants been adequately considered?	Good: ethics: when necessary, issues of confidentiality, sensitivity, and consent were addressed; bias: researcher was reflexive and/or aware of own bias.
	Fair: lip service was paid to the above (i.e., these issues were acknowledged).
	Poor: brief mention of issues.
	Very poor: no mention of issues.
7. Results: Is there a clear statement of the findings?	Good: findings are explicit, easy to understand, and in a logical progression; tables, if present, are explained in text; results relate directly to aims; sufficient data are presented to support findings.
	Fair: findings mentioned but more explanation could be given; data presented relate directly to results.
	Poor: findings presented haphazardly, not explained, and do not progress logically from results.
	Very poor: findings not mentioned or do not relate to aims.
8. Transferability or generalisability: Are the findings of this study transferable (generalisable) to a wider population?	Good: context and setting of the study are described sufficiently to allow comparison with other contexts and settings, plus a high score in Q4 (sampling).
	Fair: some context and setting described but more needed to replicate or compare the study with others, plus a fair score or higher in Q4.
	Fair: some context and setting described but more needed to replicate or compare the study with others, plus a fair score or higher in Q4.
	Very poor: no description of context/setting.
9. Implications and usefulness. How important are these findings to policy and practice?	Good: contributes something new and/or different in terms of understanding/insight or perspective; suggests ideas for further research; suggests implications for policy and/or practice.
	Fair: two of the above.
	Poor: only one of the above.
	Very poor: none of the above.

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