

# Psychedelics and Risk Assessment: Examining Self Factors through Qualitative Research

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## Abstract

Psychedelic use, within therapeutic settings and to a large extent in non-clinical use, is considered safe. However, some individuals experience distress and even enduring psychological problems following psychedelic use. Until now, psychedelic research has provided only general claims and suggestions regarding risk factors predisposing to adverse effects. Therefore, problems are usually discovered and addressed when it is too late. This article offers a general framework and rationale for preventing adverse outcomes from psychedelic use. First, it offers a multidimensional framework for understanding human consciousness and psychedelic experience, comprising 5 S's: Substance, Soma, Set, Setting, and Self. The Self signifies the more stable aspects of identity. These aspects may help in identifying risk factors for long-term adverse effects following psychedelic use. The proposed research path avoids conventional tools and favors bottom-up, qualitative (or mixed) research methods in an attempt to predict the long-term adverse effects of psychedelic use. Qualitative research may lead to the development of a psychedelic-friendly, advocacy-based, and context-sensitive research approach that will resonate with the psychedelic experience.

## INTRODUCTION

Psychedelic research and therapeutic practice are flourishing <sup>[1]</sup>. After decades of neglect and stigmatization by society, the therapeutic potential of psychedelics is being re-discovered. It is now evident that psychedelic psychotherapy can offer new, effective, and safer solutions to diverse mental health problems. The issue of safety is a major one, partly due to years of anti-psychedelic propaganda as well as documented cases of adverse effects of psychedelic use in both therapeutic and recreational settings. However, little is known about individual risk factors for such outcomes <sup>[2]</sup>. Typically, problems are discovered and addressed after the point at which an intervention would be effective.

This article offers a general framework and rationale to confront this problem. It suggests a research path that focuses on the self-concept to assess risk. This approach aims to understand better the complex

interrelations between psychedelic substances, a specific human body, set, setting, and self, and to minimize harm from psychedelic use (in therapy or elsewhere). First, the notion of set and setting and its importance will be presented along with its limitations. Next, a broader framework for understanding psychedelic experience and human consciousness in general will be sketched. Finally, the critical role of the self will be discussed within this framework for risk assessment, and potential research directions will be considered.

## SET AND SETTING AS A THEORY OF CONSCIOUSNESS

One of the significant contributions of psychedelic therapy to the general therapeutic discourse and practice is the notion of Set and Setting. As Hartogsohn <sup>[3]</sup> notes, "the idea of set and setting has been present since the early days of psychedelic therapy." Indeed, since the early 1960s, psychedelic

researchers and therapists noticed that the effect of psychedelic drugs (LSD in particular) is dependent on both internal (Set – mindset, intentions, and expectations) and external (Setting – physical, interpersonal, and cultural environment) factors <sup>[4]</sup>. Although originally <sup>[5]</sup> it also related to more stable or structural aspects of personality, it is suggested here to be distinct from situational or temporary conditions. The two aspects (stable and situational) seem to differ significantly in how they are subjectively perceived and how they may be scientifically examined. In addition, there is reason to believe that state-structural aspects of identity (trait) and situational-temporary conditions (pre-state) may influence the psychedelic experience in different ways <sup>[6]</sup>.

The effect of the Set and the Setting on the quality of the personal experience of people under the influence of psychedelics has been studied extensively, especially during the 1960s <sup>[3,7]</sup>. Reactions to psychedelics following manipulations in Set and Setting variables led to the conclusion that a variety of non-pharmacological, interrelated internal and external factors influence the personal experience and therapeutic effect.

This simple claim can be seen as revolutionary when it comes to understanding medical and psychotherapeutic processes. It marks a shift from a linear view of change processes, which distinguishes between the individual and the external environment that is usually considered to be responsible for the change. Conversely, Set and Setting are viewed here as factors that shape the individual experience (and hence play an active role in change processes) and are, in turn, being shaped by the individual. For example, depending on the individual's background, a medical setting – a hospital ward – may be experienced as safe and trustworthy, cold and impersonal, or intimidating. Each of these options is expected to affect how the individual interprets the actions taken or not taken,

views their own existing and desirable (cognitive, emotional, behavioral) responses, evaluates interpersonal interactions, and so forth. All of the above are expected to impact change processes, both medical and psychotherapeutic. Seen this way, therapy is neither exclusively dependent on the accuracy of the procedures or on professional knowledge and judgment, nor is it independent of the client's views, values, expectations, etc. Therefore, similar actions may lead to very different outcomes, depending on the interrelations between the individual's set (their preferences, expectations, and intentions) and the specific characteristics of the Setting (the physical and human environment).

One may regard the notion of Set and Setting as a foundation for understanding how human consciousness works <sup>[8]</sup> — not as a simple and closed system, but as an open and complex one, affecting the environment (and the way it is construed and hence experienced) and being affected by it. Seen as such, therapeutic processes – pharmacological and others - cannot be regarded as linear, preserving binary distinctions such as internal and external or active and passive. Surprisingly, this revolutionary idea of Set and Setting, which offers a new way of understanding therapeutic processes and human development, has had limited impact on research and discourse in related or adjacent fields.

A few studies, however, have referred to the notion of Set and Setting outside the context of psychedelic research and therapy. For example, Aton <sup>[9]</sup> focuses on sensory plasticity and discusses research findings that "have yielded fundamental insights into mechanisms by which an organism's "Set," or internal state, shapes how it experiences the external world, even at the earliest stages of sensory information processing." The author concludes: "these studies should improve our understanding of how state-dependent brain changes [...] affect how information about the world - one's setting - is encoded,

processed, stored for future use, and integrated with past experiences" (p. 13). It is proposed that the sensory system functions as a reciprocal process involving Set and Setting. Dahan <sup>[10]</sup> suggests examining the experience of childbirth in terms of Set and Setting. The author claims this prism "can help design, navigate, and explain many psychological and physiological elements of the human birth process.". Human birth, like psychedelic experiences, is not merely a physiological mechanism; rather, it is a mindful and conscious process. In the process of giving birth, a woman is mentally active in ways that may shape her experience and, at the same time, responds to the specific environment with its attributes (the Setting).

Pioneering works, such as those mentioned above, may pave the way for a significant change in how we understand human consciousness. If the mind is inherently interactive and continuously changing (or reconstructed) through reciprocal interactions with its environment, then understanding and assessing it outside a specific context is likely problematic. Disregarding essential contextual factors and data may lead to biased or false conclusions and inhibit desirable change (by over-emphasizing the influence of internal and stable factors or attributes). The result is a reductionist or oversimplified view of the human mind as a static, self-contained system. Indeed, many psychological theories have stressed the importance of the interaction between the internal subjective experience of the individual and the external objective reality. From this perspective, personal development is seen as an interactive process.

### **PSYCHEDELIC PARADIGM SHIFT AND HUMAN CHANGE PROCESSES**

Although it is clear that the notion of Set and Setting contributes significantly to the study of human consciousness and development,

both within and outside the field of psychedelic research, this framework still needs to be developed. While it does allow for an understanding of the interaction between internal and external factors and how they shape human experience, it neglects factors that may be critical in understanding the mechanisms that take part in, influence, or shape the subjective experience (including but not limited to the context of psychedelic research and therapy). Simply put, Set and Setting draw attention to the interaction between two critical facets – the internal/individual/subjective on the one hand and the external/environmental/objective on the other. Hence, at least to some extent, this conceptualization perpetuates such binary distinctions.

The underlying question here touches upon the very basis of the practice of psychiatry and psychotherapy and their assumptions regarding change. While psychiatry tends to emphasize biological explanations, psychotherapy emphasizes relationships and subjective experience. Likewise, while medical explanations of psychedelic therapy emphasize (or, in some cases, focus exclusively on) biological experience-independent mechanisms, such as molecular neuroplasticity <sup>[11]</sup>, psychotherapeutic models offer interactive explanations, such as connectedness <sup>[12]</sup>. Accordingly, Schenberg <sup>[13]</sup> discusses "the current psychiatric crisis" and the "paradigm shift in psychiatric research and development." In search of a holistic approach to psychiatry, the author offers a three-axis model integrating therapeutics, diagnostics, and understanding and states, "PAP can conceptually enrich psychiatric explanations for mental disorders and their treatment." While psychiatric research and practice may be criticized for bio-medical reductionism, psychedelic assisted psychotherapy (PAP) "can greatly contribute to the understanding of how social circumstances and adverse life experiences shape mental health and brain

activity, and how meaningful treatment experiences foster resilience."

The medical and psychotherapeutic perspectives presented above are different. The former focuses on experience-independent biological processes, while the latter offers an integrative view (e.g., body *and* mind, inside *and* outside) of psychedelic therapy. Psychedelic trials (in contrast to standard drug trials) emphasize contextual effects – including the interaction between physiology and experience – and, in this sense, resemble the psychotherapeutic perspective [14]. This research paradigm advances a complex understanding of how psychedelic therapy works. Hence, PAP may offer a more complex and holistic view of human development. This may be one of its major contributions.

However, at this point, PAP research still lacks clarity and integration: "psychedelic trials are surrounded by a cloud of conceptual confusion arising from the fact that they are simultaneously drug and psychotherapy trials" [14]. The following conceptual framework wishes to promote a more holistic understanding of psychedelic therapy and human consciousness. This model of consciousness may facilitate an interdisciplinary discussion, which seems to be needed in current psychedelic research and therapy.

## **5 S'S OF CONSCIOUSNESS**

To widen the scope of Set and Setting as a theory of consciousness, a detailed model is presented, comprising five interrelating and interactive components: Substance, Soma, Set, Setting, and Self. Each of these components represents an aspect of a holistic body-mind experience. Each of them is briefly explained below, with a particular focus on the self.

**Substance** – refers to studying substances and their possible influences on the human body and mind. This field of study is likely as old as humanity. In modern times, it

is represented by pharmacological research [15]. Within the current context of consciousness and psychotherapy, psychedelic pharmacology is an important research field that shows both promise and peril [16].

**Soma** – represents the medical research of the body and its mechanisms. Current medical research acknowledges that each body is unique and may respond differently to similar drugs and procedures. Gender medicine, for example, explores how male and female bodies respond to specific medications [17]. Personalized medicine challenges the traditional "one drug fits all" by recognizing the interaction between Substance and Soma, aspiring toward precision medicine that will enable clinicians to tailor treatment and prevention strategies to an individual's unique characteristics [18]. Thus, modern medical research and discourse acknowledge the effect of this interaction between a specific substance and a specific body.

**Set** – refers to the individual mindset prior to and throughout the psychedelic experience (e.g., intentions and expectations). Within the context of PAP, the Set (and setting, see below) plays a crucial role. Much of the effort in the initial preparatory sessions is dedicated to promoting a mindset that will support the possibility of constructive change [19].

**Setting** – in psychotherapy relates to the conditions external to the therapeutic process, including physical aspects (e.g., the clinic), duration and frequency of the sessions, payment, and more [20]. The Setting provides stability and, therefore, a sense of safety, a necessary condition for constructive change. The characteristics of the Setting may differ; however, it is important that they are discussed and agreed upon by the therapist and client. This process allows for the formation of a therapeutic contract and rapport, which can positively affect the client's state of mind. Thus, Set and Setting are related and often interact.

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**Self** – refers to the stable or structural characteristics of the personal identity (or personality traits). Baker [21] states, "the self-concept is a set of beliefs about the self that guide people's behaviour, encompassing temporal frameworks of the past, present, and future self." This is a simplification since the Self is dynamic, constantly changing, affecting, and being affected by diverse factors. Therefore, separating the Self from contextual factors is virtually impossible. However, this analytical division between the more stable and the more transient aspects of the personal experience may allow us to make helpful distinctions that will, in turn, promote our understanding of the contribution of internal and more stable factors to the psychedelic experience and consciousness in general.

It is noteworthy that in this context of psychedelic therapy, the term Self (or self-concept) should be preferred over the widely used term personality. Self-concept is "the totality of a complex, organized, and yet dynamic system of learned attitudes, beliefs, and evaluative judgments that people hold about themselves" [22]. Self-concept relates to how people view and evaluate themselves subjectively, whereas personality is assessed by others, frequently using standardized tests/questionnaires (many of which are based on the Big-5 personality traits model). Self-concept and personality signify two distinct ways to evaluate personal identity: the former is based on the subjective personal experience, and the latter draws on general statistical factor analysis findings. Hence, while the first represents a bottom-up research rationale, the second emphasizes top-down design (or, qualitative vs. quantitative research). The dynamic and integrative quality of self-concept thus lends itself to the context of psychedelic research and therapy (see elaboration below).

The above 5 S's of consciousness are, of course, interrelated. That is, each affects and is affected by the other. Therefore,

understanding change processes in general and psychedelic experience in particular, entails an examination of the *connections* between them. Focusing on each of them independently of the others is analogous to attempting to understand the experience tasting a delicious cake by examining the quality of its ingredients. Instead of analysis, this article calls for an integrative approach to the research and discourse of psychedelics and consciousness.

### PAP AND SUBJECTIVITY

The proposed integrative approach to psychedelic research and practice and the preference for subjective (i.e., Self) over objective (i.e., Big-5) terminology underscores the importance of PAP in understanding the psychedelic experience, maximizing its therapeutic potential and minimizing its risk. PAP, in its very essence, is subjective and integrative, frequently examining the interrelations between Self (or identity), Soma, Set, and Setting.

1 his inquiry of the subjective and somatic experience is beneficial on both professional and personal levels. On the more general professional research-practice level, it may advance a nuanced understanding of the mechanisms and dynamics that shape the psychedelic experience and its possible outcomes. Thus, a "detailed study of the subjective aspects of PAP has enormous consequences for the explanatory axis" [13, p. 733]. On the more personal-therapeutic level, the inquiry of the subjective psychedelic experience is productive in integrating the experience into the more stable sense of self and the individual's emotional, cognitive, behavioral, and interpersonal patterns. Integration, then, describes "the higher-level understanding of the experience and the proper application of the insights and lessons derived from it in our daily lives" [23, p. 45]. This "higher-level understanding" signifies the connection between

different aspects of the psychedelic experience. It is a crucial part of PAP and a major element in the safety of the therapeutic process.

Furthermore, the examination of the internal experience is found to have therapeutic value: "patient's subjective experience during and after the psychedelic trip seems to play an important causal role in recovering from mental illness [...] in psychiatric populations [...] as well as increases in well-being in healthy populations" [24]. As the authors note, this emphasis creates a need for phenomenological and qualitative research in PAP. As importantly, a similar subjective approach is needed prior to the psychedelic experience in an attempt to predict its outcomes and reduce harm.

## **RISK ASSESSMENT**

PAP is found to be a very safe practice, even with high doses of psychedelic substances [25]. A review of 14 clinical trials examining the benefits and risks of psychedelic therapy conducted since 1991 found that no serious adverse events have been reported [26]. Another systematic review of 34 contemporary experimental studies found that "psychedelics have been shown to be relatively safe when used with the proper preparation, supervision, and integration, but it is unclear the extent to which this generalizes to recreational use" [27]. Indeed, in the context of non-clinical use, findings are not as conclusive. Nevertheless, many studies also found that risks are relatively low and "have been exaggerated" [28].

Still, in both contexts, there is evidence that some individuals (again, depending on specific factors, i.e., Set and Setting) develop adverse reactions and experience distress [29-31]. A recent study found that 2.6% of users of classic psychedelics reported seeking medical, psychiatric, or psychological help following a challenging, difficult, or distressing

psychedelic experience [32]. Another study found enduring psychological problems (for more than one year) in 7.6% of the cases [33]. In a minority of cases, significant negative long-term consequences, such as hallucinogen persisting perception disorder or HPPD [34], have been attributed to psychedelic journeys. It is also believed that psychedelic experiences might trigger substance-induced psychosis and even schizophrenia [35].

So far, psychedelic research has produced little data and insights regarding personal-structural-psychological risk factors [2]. Our current knowledge allows us to articulate only general claims and suggestions regarding a-priori risk factors (e.g., mental illness in the family, and traumatic life experiences). As such, professional advice is no better than a common-sense reasonable guess. We should aspire toward more empirical data and evidence-based answers that will allow us to assess risk and reduce potential harm in psychedelic use, as is the norm for other mental conditions.

## **SELF, PERSONALITY, AND RISK ASSESSMENT**

There is a significant body of research examining the interrelations between psychedelics and personality. Some studies focus on the influence of personality on the psychedelic experience [36], whereas others focus on the influence of the psychedelic experience on the individual's personality [37-39]. Some studies found positive personal changes, including reduction of psychiatric symptoms, following the psychedelic experience [40; 41]. However, very few contemporary studies examined the possible connection between this interrelation (personality and psychedelics) and the risk of adverse events.

Personality (Big-5) and self-concept measures have been used to predict the individual's experience of religious/spiritual struggles and found that both are likely to

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play a role in challenging and distressing circumstances <sup>[42]</sup>. It is reasonable to assume that these factors will be relevant to the prediction of the quality of the psychedelic experience and possible adverse outcomes in particular. The findings in this field, however, are inconclusive. In their attempt to predict the effect of psychedelics (psilocybin in particular), Studerus et al. <sup>[43]</sup> found that "personality traits only marginally contributed to the prediction of psilocybin responses." The authors continue to state that "this is rather surprising because personality traits have been postulated by many authors to be among the most important determinants of hallucinogen response." However, as Haijen et al. <sup>[2]</sup> remark, this study <sup>[43]</sup> was limited to predicting the acute experience and not the long-term effects. Likewise, Barrett et al. <sup>[44]</sup> found that neuroticism is associated with challenging psychedelic experiences, but they did not examine enduring effects. Concerning future research, the authors suggest that it "may benefit from further investigation of the role of personality in predicting response to psychedelics."

Aday et al. <sup>[45]</sup> examined both state and trait factors as predictors of the response to psychedelics. Their review revealed three (related) personality traits that were most consistently linked to positive or mystical-type psychedelic drug reactions (and at the same time involved fewer adverse reactions): absorption, openness to experience, and acceptance. The authors conclude that "those high in the traits of absorption, openness, and acceptance as well as a state of surrender may represent ideal candidates for psychedelic therapy. In contrast, individuals low in those traits or that are in preoccupied, apprehensive, or confused states are more likely to experience adverse reactions." This conclusion may prove to have a potential practical value, as the authors comment: "If states and traits that facilitate the benefits of psychedelics become firmly established, then a natural

question will be how to alter those baseline variables to enhance treatment effects." A similar conclusion can be drawn here about predicting adverse effects and risk management.

In conclusion, it is necessary to explore whether the self-concept and personality traits contribute to the ability to predict adverse effects, especially long-term, of psychedelic use and to reduce harm.

### **METHODOLOGICAL DILEMMAS**

Psychedelics offer a new understanding of human experience, illness, as well as treatment and healing processes. They offer an alternative to the present hegemonic medical model of psychopathology and psychotherapy. Indeed, psychedelic research is considered revolutionary, as it may dramatically change our understanding of human life, development, interpersonal relations, society, and culture. However, psychedelics are sometimes regarded as substances used within the dominant medical experience-independent paradigm. Similarly, research focusing on the self and its interaction with the other four S's should consider the fundamental premises of the existing tools for diagnosing and evaluating personality structures (questionnaires, etc.) and their possible biases.

This discrepancy or dissonance between the medical paradigm and the research tools derived from it, on the one hand, and the quality of the specific research area of psychedelics on the other, requires a different research strategy from the traditional medical one. Indeed, it calls for a change in the research (mind)Set and Setting. As Read and Papaspyrou <sup>[46]</sup> write:

"We think that theoretical models of psyche can help us navigate the psychedelic experience, but we should not confuse the map for the territory. This danger could not be overstated:

overreliance on our favored models may constrict our perspective and limit our capacity to observe and respond to that which lies beyond our conceptual framework.”

One should be critical and even suspicious of findings related to the psychedelic experience resulting from the use of standard research tools (such as conventional personality questionnaires), which may demonstrate a different set of implicit assumptions regarding human consciousness. Among them, the view of human beings and their consciousness as relatively closed systems, of human identity as relatively static, and of human development as relatively linear. As previously mentioned, western theories and research on personality tend to study individual identity by analyzing it and breaking it down into its basic elements or "ingredients." In contrast, psychedelic experience tends to emphasize connectedness and a holistic quality that the term Self better represents. For psychedelic research and therapy to be coherent, there must be consistency between and within concepts and tools. Thus, instead of top-down research aspiring for generalizations, a bottom-up approach seeking differences and outliers is more useful and appropriate here.

In other words, qualitative research tools may be valuable and constructive in the process of developing a psychedelic-friendly, advocacy-based, and context-sensitive research approach that will resonate with the psychedelic experience.

### **QUALITATIVE RESEARCH AND PSYCHEDELICS**

In a systematic review of qualitative research examining experiences of psychedelic treatments for psychiatric disorders Brecksema et al. [47] state:

“Exploring patient experiences can increase our understanding of underlying

therapeutic mechanisms and processes, the role of (extra) pharmacological factors in these treatment modalities, which may contribute to optimizing treatment context, and lead to improved clinical responses and personal benefits.”

In a more recent study examining adverse events in clinical treatments, the authors discuss the challenges in assessing adverse events (particularly acute ones), partly because some of them were retrospectively evaluated as therapeutic and beneficial [48]. The authors note that “qualitative research can also add nuance by detailing and understanding the meaning of challenging experiences.” So, qualitative research may offer a better vantage point into the complex psychedelic experience, the factors shaping it, and its aftereffects. It may allow us to make valuable distinctions, for example, between stable (Self) and situational (Set) personal qualities or between different external influences (Substance and Setting). More importantly, personal narratives and other qualitative data may help us consolidate the contribution of different factors (the 5 S's) into one integrative narrative.

Moreover, qualitative research (or combined mixed method research) may contribute uniquely to the understanding of the therapeutic processes within PAP and to the possibility of formulating a bottom-up, grounded theory [49] of PAP. In this growing field that is considered by many to represent a possible paradigm shift in medicine and psychotherapy, this kind of open-minded and humble stance is crucial.

### **CONCLUSION**

While concerns about the safety of psychedelic use in clinical and recreational settings persist, little is known about the factors contributing to the risk of adverse outcomes. This article discusses the importance of the



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notion of Set and Setting as a theory of consciousness and explores its limitations in this context. It offers a nuanced conceptual framework of consciousness, comprising 5S's – Substance, Soma, Set, Setting, and Self – all of which affect the psychedelic experience. This framework emphasizes the complex interrelations between the components rather than the quality and potency of each of them separately.

Within this general framework, the importance of the Self, or the stable personality attributes of the individual, is underlined. We argue that focusing on this component and how it interacts with others may help us develop means to predict the quality of the psychedelic experience. More specifically, it may advance our knowledge and understanding of long-term adverse effects and contribute to risk assessment and harm reduction efforts.

While research in this field must be critical of conventional tools assessing personality, we stress that qualitative research is critical in the pursuit of understanding the complex psychedelic experience, the factors shaping it, and its aftereffects. Qualitative research may play a key role in the endeavor to develop new theories and research tools that resonate with the psychedelic experience and help to realize the promise of a paradigm shift attributed to psychedelic research and therapy.

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### REFERENCES

1. Hadar, A., David, J., Shalit, N., Roseman, L., Gross, R., Sessa, B., & Lev-Ran, S.

- (2023). The psychedelic renaissance in clinical research: a bibliometric analysis of three decades of human studies with psychedelics. *Journal of psychoactive drugs*, 55(1), 1-10.
2. Haijen, E. C., Kaelen, M., Roseman, L., Timmermann, C., Kettner, H., Russ, S., & Carhart-Harris, R. L. (2018). Predicting responses to psychedelics: a prospective study. *Frontiers in pharmacology*, 897.
3. Hartogsohn, I. (2020). *American trip: set, setting, and the psychedelic experience in the twentieth century*. MIT Press.
4. Hartogsohn, I. (2017). Constructing drug effects: A history of set and setting. *Drug Science, Policy and Law*, 3, 2050324516683325.
5. Leary, T., Litwin, G. H., & Metzner, R. (1963). Reactions to psilocybin administered in a supportive environment. *The Journal of nervous and mental disease*, 137(6), 561-573.
6. Carhart-Harris, R. L., Roseman, L., Haijen, E., Erritzoe, D., Watts, R., Branchi, I., & Kaelen, M. (2018). Psychedelics and the essential importance of context. *Journal of psychopharmacology*, 32(7), 725-731.
7. Hartogsohn, I. (2016). Set and setting, psychedelics and the placebo response: an extra-pharmacological perspective on psychopharmacology. *Journal of Psychopharmacology*, 30(12), 1259-1267.
8. Rankaduwa, S., & Owen, A. M. (2023). Psychedelics, entropic brain theory, and the taxonomy of conscious states: a summary of debates and perspectives. *Neuroscience of consciousness*, 2023(1), 1-13.
9. Aton, S. J. (2013). Set and setting how behavioral state regulates sensory function and plasticity. *Neurobiology of Learning and Memory*, 106, 1-10.
10. Dahan, O. (2023). Navigating intensive altered states of consciousness: How can the set and setting key parameters

- promote the science of human birth?. *Frontiers in Psychiatry*, 14.
11. Ly, C., Greb, A. C., Cameron, L. P., Wong, J. M., Barragan, E. V., Wilson, P. C., ... & Olson, D. E. (2018). Psychedelics promote structural and functional neural plasticity. *Cell reports*, 23(11), 3170-3182.
  12. Carhart-Harris, R. L., Erritzoe, D., Haijen, E. C. H. M., Kaelen, M., & Watts, R. (2018). Psychedelics and connectedness. *Psychopharmacology*, 235, 547-550.
  13. Schenberg, E. E. (2018). Psychedelic-assisted psychotherapy: a paradigm shift in psychiatric research and development. *Frontiers in pharmacology*, 9, 733.
  14. Nayak, S., & Johnson, M. W. (2021). Psychedelics and psychotherapy. *Pharmacopsychiatry*, 54(04), 167-175.
  15. Braslow, J. T., & Marder, S. R. (2019). History of psychopharmacology. *Annual review of clinical psychology*, 15, 25-50.
  16. McClure-Begley, T. D., & Roth, B. L. (2022). The promises and perils of psychedelic pharmacology for psychiatry. *Nature reviews Drug discovery*, 21(6), 463-473.
  17. Baggio, G., Corsini, A., Floreani, A., Giannini, S., & Zagonel, V. (2013). Gender medicine: a task for the third millennium. *Clinical Chemistry and Laboratory Medicine (CCLM)*, 51(4), 713-727.
  18. Thibaut, F. (2022). From basic research to personalized medicine. *Dialogues in Clinical Neuroscience*.
  19. Wolfson, E. (2023). Psychedelic-supportive psychotherapy: A psychotherapeutic model for, before and beyond the medicine experience. *Journal of Psychedelic Studies*, 6(3), 191-202.
  20. Laor, I. (2007). The therapist, the patient, and the therapeutic setting: Mutual construction of the setting as a therapeutic factor. *Psychoanalytic Dialogues*, 17(1), 29-46.
  21. Baker, F. A., Tamplin, J., Rickard, N., Ponsford, J., New, P. W., & Lee, Y. E. C. (2019). A therapeutic songwriting intervention to promote reconstruction of self-concept and enhance well-being following brain or spinal cord injury: pilot randomized controlled trial. *Clinical Rehabilitation*, 33(6), 1045-1055.
  22. Wehrle, K., & Fasbender, U. (2019). Self-concept. *Encyclopedia of personality and individual differences*, 3-5.
  23. Aixala, M. B. (2022). *Psychedelic integration: Psychotherapy for non-ordinary states of consciousness*. Synergetic Press.
  24. Miceli McMillan, R., & Fernandez, A. V. (2022). Understanding subjective experience in psychedelic-assisted psychotherapy: The need for phenomenology. *Australian & New Zealand Journal of Psychiatry*, 00048674221139962.
  25. Nicholas, C. R., Henriquez, K. M., Gassman, M. C., Cooper, K. M., Muller, D., Hetzel, S., & Hutson, P. R. (2018). High dose psilocybin is associated with positive subjective effects in healthy volunteers. *Journal of psychopharmacology*, 32(7), 770-778.
  26. Bender D, Hellerstein DJ. Assessing the risk-benefit profile of classical psychedelics: a clinical review of second-wave psychedelic research. *Psychopharmacology (Berl)*. 2022 Jun;239(6):1907-1932. doi: 10.1007/s00213-021-06049-6. Epub 2022 Jan 13. PMID: 35022823.
  27. Aday, J. S., Mitzkovitz, C. M., Bloesch, E. K., Davoli, C. C., & Davis, A. K. (2020). Long-term effects of psychedelic drugs: A systematic review. *Neuroscience & Biobehavioral Reviews*, 113, 179-189.
  28. Letheby, C. (2021). *Philosophy of psychedelics*. Oxford University Press.
  29. Dos Santos, R. G., Bouso, J. C., Alcázar-Córcoles, M. Á., & Hallak, J. E. (2018). Efficacy, tolerability, and safety of serotonergic psychedelics for the

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- management of mood, anxiety, and substance-use disorders: a systematic review of systematic reviews. *Expert review of clinical pharmacology*, 11(9), 889-902.
30. Leonard JB, Anderson B, Klein-Schwartz W. Does getting high hurt? Characterization of cases of LSD and psilocybin-containing mushroom exposures to national poison centers between 2000 and 2016. *Journal of Psychopharmacology*. 2018;32(12):1286-1294. doi:10.1177/0269881118793086
  31. Bienemann, B., Ruschel, N. S., Campos, M. L., Negreiros, M. A., & Mograbi, D. C. (2020). Self-reported negative outcomes of psilocybin users: A quantitative textual analysis. *PLoS One*, 15(2), e0229067.
  32. Simonsson, O., Hendricks, P. S., Chambers, R., Osika, W., & Goldberg, S. B. (2023). Prevalence and associations of challenging, difficult or distressing experiences using classic psychedelics. *Journal of Affective Disorders*, 326, 105-110.
  33. Carbonaro, T. M., Bradstreet, M. P., Barrett, F. S., MacLean, K. A., Jesse, R., Johnson, M. W., & Griffiths, R. R. (2016). Survey study of challenging experiences after ingesting psilocybin mushrooms: Acute and enduring positive and negative consequences. *Journal of psychopharmacology*, 30(12), 1268-1278.
  34. Schlag, A. K., Aday, J., Salam, I., Neill, J. C., & Nutt, D. J. (2022). Adverse effects of psychedelics: From anecdotes and misinformation to systematic science. *Journal of Psychopharmacology*, 36(3), 258-272.
  35. Murrie, B., Lappin, J., Large, M., & Sara, G. (2020). Transition of substance-induced, brief, and atypical psychoses to schizophrenia: a systematic review and meta-analysis. *Schizophrenia bulletin*, 46(3), 505-516.
  36. Bouso, J. C., Palhano-Fontes, F., Rodríguez-Fornells, A., Ribeiro, S., Sanches, R., Crippa, J. A. S., ... & Riba, J. (2015). Long-term use of psychedelic drugs is associated with differences in brain structure and personality in humans. *European Neuropsychopharmacology*, 25(4), 483-492.
  37. Bouso, J. C., Dos Santos, R. G., Alcázar-Córcoles, M. Á., & Hallak, J. E. (2018). Serotonergic psychedelics and personality: A systematic review of contemporary research. *Neuroscience & Biobehavioral Reviews*, 87, 118-132.
  38. Erritzoe, D., Smith, J., Fisher, P. M., Carhart-Harris, R., Frokjaer, V. G., & Knudsen, G. M. (2019). Recreational use of psychedelics is associated with elevated personality trait openness: Exploration of associations with brain serotonin markers. *Journal of Psychopharmacology*, 33(9), 1068-1075.
  39. Johnstad, P. G. (2021). The psychedelic personality: Personality structure and associations in a sample of psychedelics users. *Journal of psychoactive drugs*, 53(2), 97-103.
  40. Kettner, H., Rosas, F. E., Timmermann, C., Kärtner, L., Carhart-Harris, R. L., & Roseman, L. (2021). Psychedelic communities: intersubjective experience during psychedelic group sessions predicts enduring changes in psychological well-being and social connectedness. *Frontiers in Pharmacology*, 234.
  41. Mans, K., Kettner, H., Erritzoe, D., Haijen, E. C., Kaelen, M., & Carhart-Harris, R. L. (2021). Sustained, multifaceted improvements in mental well-being following psychedelic experiences in a prospective opportunity sample. *Frontiers in psychiatry*, 12, 647909.
  42. Grubbs, J. B., Wilt, J., Stauner, N., Exline, J. J., & Pargament, K. I. (2016). Self, struggle, and soul: Linking personality, self-concept, and religious/spiritual

- struggle. *Personality and Individual Differences*, 101, 144-152.
43. Studerus, E., Gamma, A., Kometer, M., & Vollenweider, F. X. (2012). Prediction of psilocybin response in healthy volunteers. *PloS one*, 7(2), e30800.
  44. Barrett, F. S., Johnson, M. W., & Griffiths, R. R. (2017). Neuroticism is associated with challenging experiences with psilocybin mushrooms. *Personality and individual differences*, 117, 155-160.
  45. Aday, J. S., Davis, A. K., Mitzkovitz, C. M., Bloesch, E. K., & Davoli, C. C. (2021). Predicting reactions to psychedelic drugs: A systematic review of states and traits related to acute drug effects. *ACS Pharmacology & Translational Science*, 4(2), 424-435.
  46. Read, T. & Papaspyrou, M. (2021). Into the deep: Integrating psychedelics and psychotherapy. In T. Read & M. Papaspyrou (Eds.), *Psychedelics & psychotherapy: The healing potential of expanded states* (pp. xix-xxvi). Park Street Press.
  47. Breeksema, J. J., Niemeijer, A. R., Krediet, E., Vermetten, E., & Schoevers, R. A. (2020). Psychedelic treatments for psychiatric disorders: a systematic review and thematic synthesis of patient experiences in qualitative studies. *CNS drugs*, 34, 925-946.
  48. Breeksema, J. J., Kuin, B. W., Kamphuis, J., van den Brink, W., Vermetten, E., & Schoevers, R. A. (2022). Adverse events in clinical treatments with serotonergic psychedelics and MDMA: A mixed-methods systematic review. *Journal of Psychopharmacology*, 36(10), 1100-1117.
  49. Strauss, A., & Corbin, J. (1990). *Basics of qualitative research*. Sage.

