With Great Power Comes Great Vulnerability: An Ethical Analysis of Psychedelics' Therapeutic Mechanisms Proposed by the REBUS Hypothesis

Daniel Villiger & Manuel Trachsel

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ABSTRACT

Psychedelics are experiencing a renaissance in mental healthcare. In recent years, more and more early phase trials on psychedelic-assisted therapy have been conducted, with promising results overall. However, ethical analyses of this rediscovered form of treatment remain rare. The present paper contributes to the ethical inquiry of psychedelic-assisted therapy by analysing the ethical implications of its therapeutic mechanisms proposed by the REBUS hypothesis. In short, the REBUS hypothesis states that psychedelics make rigid beliefs revisable by increasing the influence of bottom-up input. Put differently, patients become highly suggestible and sensitive to context during a psychedelic session, amplifying therapeutic influence and effects. Due to that, patients are more vulnerable in psychedelic-assisted therapy than in other therapeutic interventions; they lose control during a psychedelic session and become dependent on the therapeutic setting (including the therapist). This enhanced vulnerability is ethically relevant and has been exploited by some therapists in the past. Therefore, patients in current research settings and starting mainstream medical settings need to be well-informed about psychedelics' mechanisms and their implications to give valid informed consent to treatment. Furthermore, other security measures are warranted to protect patients from the vulnerability coming with psychedelic-assisted therapy.

1 INTRODUCTION

Psychedelics have re-entered the stage of mental healthcare [1,2]. The regained interest in psychedelics is mainly due to promising results of early phase trials: (1) psilocybin-assisted psychotherapy seems to be effective in reducing symptoms of cancer-related depression and anxiety as well as treatment-resistant depression (TRD) [3–9]. Moreover, there is first evidence suggesting that psilocybin is beneficial in smoking and alcohol cessation treatment [10–13]. (2) A trial with lysergic acid diethylamide (LSD) assisted psychotherapy suggests effectiveness in treating anxiety associated with life-threatening diseases [14]. Besides, a meta-analysis of randomized controlled trials of LSD-assisted treatment conducted between 1966 and 1970 found beneficial effects of LSD on alcohol abuse [15]. (3) N,N-dimethyltryptamine (DMT), which is the active psychedelic substance in Ayahuasca, seems to have therapeutic effects in the context of TRD [16,17]. Due to these promising early results, classic serotonergic psychedelics (i.e. psilocybin, LSD, and DMT) are attributed great potential in mental healthcare (for a systematic review of their therapeutic effects, see [18]).

Despite the widespread excitement about the psychedelic renaissance, there are also less enthusiastic findings: a recent phase 2 study did not find that assisting a therapy for depression with psilocybin is significantly more effective than with escitalopram [19]; and treatment effect sizes in psychedelic randomized control trials are assumed to be overestimated due to blinding problems and response expectancy [20]. Consequently, some authors think that there currently exists a 'psychedelic hype bubble' with inflated expectations [21]. In addition, they have bluntly warned that the 'superenthusiasts are incorrect in believing that psychedelics pose no risks because those risks are well established' [21]. In this line, Smith and Sisti [22] have raised ethical concerns, comprising that 'psychedelics pose certain novel risks, which warrant an enhanced informed consent process–one that is more comprehensive than what may be typical for other psychiatric medications.' (p. 807) The authors derive these novel risks from the fact that *psychedelic-assisted therapy* (PAT) can lead to a shift in values and personality [23–25], likely involves therapeutic touch [26], and comes with mental health risks – although rarely (e.g. severe anxiety, psychosis, and trauma re-exposure) [4,27]. They also emphasise the uniqueness of psychedelics' mechanisms and suggest that patients should be informed about them. However, they do not further elaborate the details of these mentioned mechanisms and why they are ethically relevant.

This is where the present paper draws on. It extends the ethical inquiry of PAT by scrutinizing its mechanisms of action. Currently, there are three models describing the

neurocognitive mechanisms of psychedelics (which are not necessarily mutually exclusive) [cf. 28–30]: the cortico-striato-thalamo-cortical (CSTC) theory [31,32], the relaxed beliefs under psychedelics (REBUS) hypothesis [33], and the claustro-cortical circuit (CCC) model [29]. This paper concentrates on the *REBUS hypothesis* for two reasons: First, among the three available models, it is the only one that has a major focus on psychedelics' therapeutic effects and that has already been expanded on PAT [34]. Second, the REBUS hypothesis seems to have the greatest empirical support so far: Carhart-Harris and Friston [33] present various indirect evidence for the REBUS hypothesis and recent studies provide further indirect and also more direct evidence for it [35–38]. The other two models do not (yet) come with such a comprehensive body of evidence. Furthermore, a recent systematic review on default mode network modulation by psychedelics finds that most studies support the REBUS hypothesis [28]. Nonetheless, it is important to notice that even though the REBUS hypothesis has the greatest empirical support so far, additional confirmatory research is still needed to thoroughly test its predictions. Therefore, some assumptions of the REBUS hypothesis might ultimately turn out to be wrong. However, even if that were the case, the ethical implications discussed in this paper would likely still be valid as they build on widely accepted characteristics of psychedelics [cf. 39–44] which the REBUS hypothesis has integrated into a grander theory.

The remainder of the paper is structured as follows: The first part presents the REBUS hypothesis and the framework on which it builds, namely predictive processing, in more detail. The second part then discusses the ethical implications of the REBUS hypothesis.

2 HOW PSYCHEDELICS WORK: THE REBUS HYPOTHESIS

Classic serotonergic psychedelics exert their effects primarily by cortical serotonin 2A receptor (5-HT2AR) agonism. This can be inferred from the finding that taking a 5-HT2AR antagonist first and a psychedelic second substantially weakens its typical phenomenological effects [45]. As 5-HT2AR agonism plays such a dominant role in psychedelics' pharmacological mechanisms of action, this is where we should also find the reason for psychedelics therapeutic effects.

To explain the role of 5-HT2ARs in our brain and, in this way, the therapeutic mechanisms of psychedelics, the REBUS hypothesis builds on two theories: the free-energy principle and the entropic brain hypothesis. The *free-energy principle* is a unified description of biological systems' behaviour and tries to explain their ability to resist a natural tendency to disorder and thereby self-dissolvement [46–48]. Applied to humans, the free-energy principle is often associated with predictive processing, which is a Bayesian approach to the brain that has

become increasingly influential in the last decade [49–52]. *Predictive processing* describes the brain as an active probabilistic prediction machine: instead of building up the incoming sensory input stepwise to a complete percept of what is out there, the brain generates a percept by using its best predictions of what is likely to be out there. Consequently, what we perceive is not the bottom-up sensory input itself but recurrent cascades of top-down predictions (stemming from the brain's generative model of the world) that try to predict the sensory input. These predictions are hierarchically organized, with high spatial and temporal preciseness at lower levels and increasing abstractness at higher levels. Across all these levels, the goal is to minimise accumulated prediction error that results from mismatches between top-down predictions and bottom-up sensory input. Thereby, mismatches can be handled in two general (non-exclusive) ways: the brain adjusts its predictions to the sensory input and thereby updates its generative model (called *perceptual inference*) or it acts upon its environment (including the body) such that the resulting sensory input aligns to prior predictions (called *active inference*). To what extent each applies depends on the precision assigned to the prediction and the sensory input: the less precise the prediction is estimated to be, relative to the current sensory input, the more dominant perceptual inference becomes (and vice versa) [53,54].

From a physiological perspective, pyramidal cells are hypothesized to play a key role regarding such precision weighting, with superficial pyramidal cells being associated with the precision of sensory input and deep pyramidal cells with the precision of predictions [55–57]. According to the REBUS hypothesis, psychedelics act primarily through stimulating 5-HT2ARs on deep pyramidal cells which disinhibits or sensitizes these cells and thereby attenuates the precision of predictions. In turn, this results in a stronger influence of bottom-up sensory input.

The cortex and, particularly, the visual cortex and high-level association regions have the densest expression of 5-HT2ARs and should therefore be most strongly affected by psychedelics [33,58]. This offers an explanation why psychedelics can lead to such ineffable experiences. High-level association regions are thought to involve high-level predictions that comprise our most fundamental assumptions. Mitigating the precision of these predictions means shaking our very foundations [51]. For instance, the default-mode network (DMN) constitutes such a high-level association region and is linked to self-consciousness [59]. From a predictive processing perspective, we can say that DMN forms the prediction that we are a consistent and independent entity; a prediction which is given high precision. Psychedelics should weaken the precision of this prediction, which can ultimately lead to what is known as *ego dissolution* [60]. So, in a nutshell, the REBUS hypothesis supposes that psychedelics reduce the precision of

high-level predictions (sometimes also called *hyperpriors*) and in so doing increase the impact of bottom-up sensory input (see Figure 1).

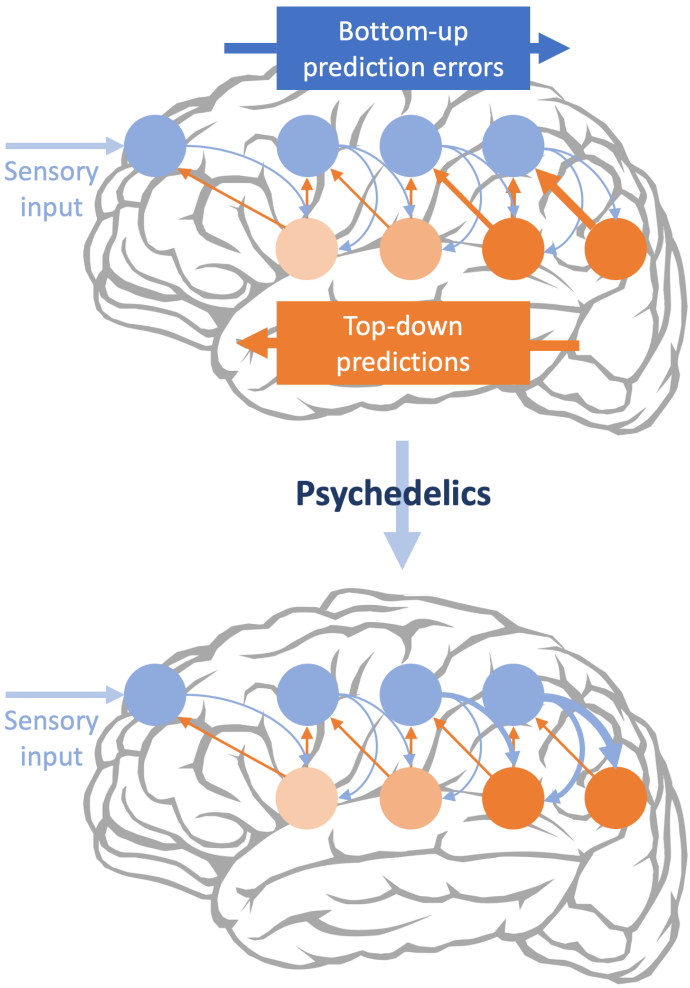

Figure 1: Schematic illustration of the REBUS hypothesis (adapted from Carhart-Harris and Friston [33]). In the 'normal' brain, high-level top-down predictions have a strong influence on the resolution of bottom-up prediction errors (illustrated through thicker arrows), inhibiting these errors from flowing upwards the processing hierarchy. Because of that, high-level top-down predictions do not get updated in the presence of disconfirming sensory input. Through stimulating 5-HT2ARs on deep pyramidal cells, psychedelics decrease the precision of high-level top-down predictions which liberates bottom-up prediction errors to flow upwards (illustrated through shrinking orange arrows and greatening blue arrows in the hierarchy's higher levels). In turn, this amplifies the influence of the bottom-up sensory input and enables the revision of high-level top-down predictions.

To understand why the reduction of high-level predictions' precision is believed to have therapeutic effects, we must look at the second theory on which the REBUS hypothesis builds: *the entropic brain hypothesis* (see Figure 2). It states that in healthy adults' normal waking consciousness, the entropic state of the brain is at a point where cognition is ordered but still somewhat flexible [61,62]. Using this point as a reference, if entropy increases, cognition gets more flexible but also more disordered: a state that early psychosis is thought to involve. Alternatively, if entropy decreases, the brain enters states of higher order but also higher rigidity.

According to the entropic brain hypothesis, mental disorders such as depression, obsessive compulsive disorder (OCD), anxiety, and addiction are linked to such states. Here, due to tight order, the brain cannot switch from the dysfunctional state to a more functional one, even in the presence of new experiences. In other words, the brain is trapped [63,64]. This is where psychedelics should provide remedy: they are hypothesized to increase entropy of spontaneous brain activity which results in a more interconnected and flexible brain [65–71]. Accordingly, the brain can escape the tight order that is assumed to come with certain mental disorders.

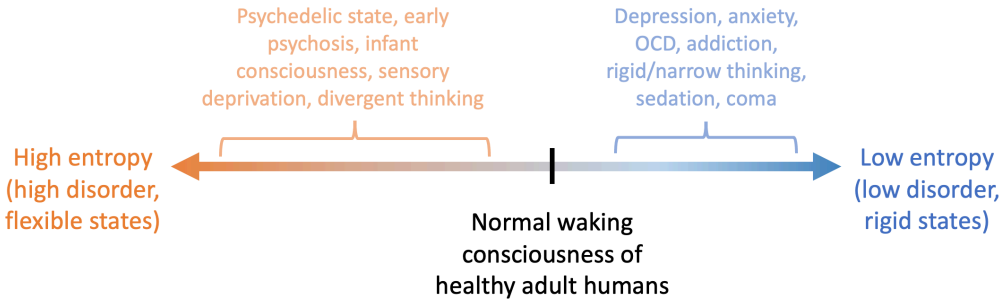

Figure 2: Schematic illustration of the entropic brain hypothesis (adapted from Carhart-Harris et al. [63]). The normal waking consciousness of healthy adult humans is slightly below the midpoint between high and low entropy (which is called criticality proper). States of lower entropy come with lower disorder but also stronger rigidity. Various mental disorders such as depression, anxiety, OCD, and addiction are associated with such states. Conversely, states of higher entropy come with higher disorder but also higher flexibility. Being under psychedelics is associated with such states. Because of that, psychedelics are assumed to enable the brain to escape the tight order that come with certain mental disorders.

If we translate the entropic brain hypothesis into predictive processing terms, we get the following assumptions: mental disorders such as depression, OCD, anxiety, and addiction are the product of overly precise high-level predictions (for predictive processing accounts on these mental disorders, see [72–76]). Because of their excessive precision, bottom-up sensory input is inhibited and unsensitized, impeding the updating of predictions in the presence of disconfirming sensory input [33,77]. Psychedelics are hypothesized to weaken this rigidity by decreasing the precision and thereby the influence of high-level predictions (including dysfunctional ones). In so doing, they raise the entropy of spontaneous brain activity and enable brain states that were blocked before by top-down override.

Carhart-Harris and Friston [33] call the brain's state under psychedelics the 'anarchic brain'. The term *anarchic* refers to the fact that the precision of high-level predictions is mitigated and, consequently, bottom-up sensory input liberated to flow upwards the processing hierarchy. Here, normally inhibited bottom-up signalling from lower-level intrinsic systems (e.g. the limbic system) seem to be especially implicated in the action of psychedelics [63,65,78].

Accordingly, their disinhibition under psychedelics can explain the intense and overwhelming emotional experiences that typically come along with taking psychedelics [39]. More generally, it was found that the anarchic brain is more suggestible and sensitive to context [79,80] and has increased synaptic plasticity and efficacy [81]. So, the anarchic brain provides perfect conditions for the revision of high-level predictions. And if the brain does not revert to its rigid and dysfunctional previous states after the psychedelic experience but stays more flexible (however, also not too flexible), there should be long-term therapeutic effects.

Ultimately, the REBUS hypothesis leads to the following implication: whether the revisions of high-level predictions are successful from a therapeutic perspective depends on the bottom-up signalling inducing them. An important part of this bottom-up signalling stems from the therapeutic environment. Therefore, in PAT, therapeutic influence and dependency on the therapeutic setting increases [34].

3 ETHICAL IMPLICATIONS

As we will show in this section, the enhanced suggestibility in PAT suggested by the REBUS hypothesis is ethically relevant in current research settings as well as starting mainstream medical settings (as from 2023, the US state of Oregon legalised psilocybin, making it available for treatment [82]). By putting the patient into a state where high-level predictions become revisable, therapists can to some degree influence the direction of the revisions through the bottom-up input they produce (e.g. therapeutic setting, verbal interactions, etc.). At this, it is harder to avoid influence when under psychedelics compared to other medications: a major advice when having a psychedelic experience is to surrender to it or, to cite a common mantra, to trust, let go, and be open [39]. Trying to fight back the psychedelic experience is typically counter-productive as the benefits are thought to be enabled by not fighting the experience [41]. Therefore, during the psychedelic state, patients are to some extent at the mercy of their therapist. And since it is also during this state that patients' brains become anarchic and their high-level predictions revisable, the therapist can exert impact over the revision process. Admittedly, therapist-patient interactions are relatively rare during a psychedelic session, at least in current research settings (extralegal settings might differ in this regard). However, the attenuation of high-level predictions might not directly end after the acute psychedelic hot state. In fact, Carhart-Harris and Friston [33] assume that the acquisition and integration of new insights occur after the psychedelic experience. Since therapists typically accompany this process in the form of integration sessions they can exercise influence over it [cf. 34]. Finally, already a single high-

dose psychedelic session has the potential to substantially revise high-level predictions and to make a very lasting impression [42,83]. Therefore, even in one-time PAT, patients undergo an experience whose unfolding and impact they cannot really control (or anticipate), and which simultaneously increases therapeutic influence.

If we compare PAT with other treatments, we realize that the form of power which therapists have over patients during the psychedelic session is unique (see Table 1). In general, the goal of treatment from a predictive processing perspective is the revision of dysfunctional predictions [33]. However, different treatments have different revision processes, coming with different potentials to exert impact on the patient. To mention three such other treatments: First, in typical pharmacological treatments, patients take the psychotropic drug on a regular basis, with remedial effects appearing immediately or after some time and vanishing when the drug is no longer taken. This gives patients control over the overall revision process as they can stop taking the drug at any time and thereby reverse revisions. The practitioner can only exert power over the patient by stopping or changing the drug prescription. Second, in psychotherapy, the patient-therapist-relationship is assumed to build the basis for the revision of dysfunctional predictions [34,84]. Due to the importance of the therapeutic bond, the therapist has influence on the revision process, which opens the door for exerting impact on the patient. However, since the revision process in psychotherapy is rather slow and takes months if not years, patients largely remain in control over their revisions and can stop therapy any time. Third, in electroconvulsive therapy (ECT), patients are under general anaesthesia and thus to some extent at the mercy of their practitioner [85]. But since ECT induces a medium-fast revision process, patients still have control over the overall treatment as they can refuse further administrations. Moreover, the practitioner administering ECT cannot influence the direction of revisions. Thus, their potential impact is limited to prescribing and administering ECT. In contrast, in PAT, the patient (1) does not benefit from fighting back the psychedelic experience, (2) the therapist can to some degree influence the direction of revisions, and (3) a single session can be sufficient for such revisions. Thus, compared to the other three treatments, the therapist's ability to exert impact on the patient is enhanced in PAT.

Table 1 Comparison of different treatments regarding practitioners' potential impact

	Psychotropics	**Psychotherapy**	**Electroconvulsive therapy (ECT)**	**Psychedelic-assisted therapy (PAT)**
Frequency of treatment	Regular intake	Regular sessions, typically weekly	2-3 times per week, 3-6 weeks	One or more doses with several weeks in between

Duration until effects	From immediately to after a few weeks	After several weeks or months	After several administrations	Immediately
Practitioner's control over revisions	Null; can only stop prescription	Can exercise partial influence on revisions	Null; can only stop administration	Can exercise partial influence on revisions
Patient's control over revisions	Largely in control over revisions since they are not long-lasting	Largely in control over revisions since they are rather slow	Largely in control over revisions since they are not so fast	Little in control over revisions since they are both overwhelming and potentially long-lasting

Importantly, the unique potential impact that comes with PAT also makes it such a promising intervention. Psychedelics have been described as a non-specific amplifier of what is already there [39,86,87]. This is why set (i.e. the mental state a person brings to the experience) and setting (i.e. the physical and social environment during the experience) are of utmost importance during a psychedelic session [40,43,44]. And since a psychotherapeutic intervention embeds the psychedelic session, the therapist substantially co-defines the patient's set and setting. This is hypothesized to be what makes psychedelics and psychotherapy such a promising combination: psychedelics function as an amplifier of psychotherapeutic mechanisms and effects [34]. Given that this is true, psychedelics could also increase some of the ethical challenges of psychotherapy.

A qualitative exploration of relational ethical challenges and practices in PAT seems to highlight these psychedelic-based amplifications [88]. The authors interviewed 23 practitioners who have administered psilocybin and 3,4-methylenedioxymethamphetamine (MDMA) to clients in extralegal settings. Among others, these practitioners note that, compared to talk therapy, PAT gives: greater degree of transference (e.g. sexual desire for the therapist or 'guru projections' in which the patient ascribes great wisdom or power to the therapist) and countertransference (e.g. reinforcement of patient's guru projections); greater client vulnerability (e.g. reduced ability to act self-protectively); impaired autonomy (e.g. impossibility to give in-session solicitations of consent); and greater sensitivity to therapist's material (e.g. patients having greater than usual capacity to sense the inner experience of the therapist).[1]

A treatment that enables therapists to exert impact on patients can be misused. Unfortunately, such misuse has happened and is still happening. For example, in 1986, the Swiss psychiatrist Samuel Widmer got a special permit from the Swiss Federal Office of Public Health

[1] However, it is not entirely clear how well these findings generalise to legal PAT, as they refer to both psilocybin and MDMA sessions and as practices in extralegal settings might generally differ from practices in legal settings.

(FOPH) to use psychedelics for research purposes. Due to malpractice, the FOPH revoked the special permit seven years later, yet Widmer continued to use psychedelics in his therapeutic work and founded a community called *Cherry Blossom Community*. This community has cult-like features and offers both therapeutic help and training in treatment with psychedelics, which led to a network of underground practitioners continuing Widmer's therapeutic approach. There are reports of community escapists and former patients which show how the mechanisms of psychedelics can be misused, pointing to potential ethical concerns in legal PAT [89,90]. For example, a community escapist said about the psychedelic sessions: '[E]verything is controlled from the very beginning. So, I remember a very threatening film score from a Vietnam movie – "The Thin Red Line" – and if you listen to it on LSD, it's not so funny. Music like that doesn't evoke happy associations, but rather fear and discomfort, things that reinforce the idea that you're not good enough, that you need to work on yourself a lot more. That's how they keep you at it.' [90]

Smith and Sisti [22] have already argued that PAT requires an informed consent process that is more comprehensive than what may be typical for other psychiatric medications. Unlike other psychiatric medications, PAT can lead to a shift in values and personality, likely involves therapeutic touch (for respective guidelines, see [22]), and comes with rare mental health risks. Appealing to the reasonable person standard in ethics, the authors argue that patients want to be informed about these specific features of PAT, requiring an enhanced informed consent process. We agree with Smith and Sisti [22] and, by analysing the therapeutic mechanisms of psychedelics proposed by the REBUS hypothesis, provide further reasons for an enhanced informed consent process: being under psychedelics makes patients more open to therapeutic influence and, since they simultaneously lose control over their state, also more vulnerable; patients do not benefit from fighting back the psychedelic experience; and a single session can be sufficient for lasting changes. The loss of control and increased influence of the therapeutic setting (including the therapist) which is not present to such extent in other therapeutic interventions are features of PAT that are likely relevant for the decision of a reasonable patient. This is because patients might not want to undergo an experience whose unfolding and impact they cannot really control (or anticipate) and/or might not want to be in a state where their therapist can exercise substantial influence over them.

While such an enhanced informed consent process informs patients about the vulnerability coming with PAT, it does neither prepare them for nor protect them from it. Therefore, we briefly outline three other potential measures (see Table 2): (1) preparatory sessions make the patient familiar with the therapeutic setting and the therapist. This helps the patient to assess whether they feel comfortable enough to let themselves in for the vulnerable state coming with

psychedelics. (2) Starting PAT with a lower-than-standard dosage reduces the patient's vulnerability in the first psychedelic session. This way, the patient gets a first impression of a (mild) psychedelic experience and its implications and can then decide whether they want to continue with the standard dosage. (3) Specific training and oversight of psychedelic therapists should minimize malpractice cases of PAT where therapists exploit the vulnerability of patients induced by psychedelics.

Table 2 Security measures regarding enhanced vulnerability in PAT

Enhanced informed consent process (in addition to the suggestions of Smith and Sisti [22])	Patients get informed about the enhanced vulnerability in PAT with disclosure information such as: *Psychedelics are assumed to put you in a state where rigid beliefs and values become revisable. However, you cannot really control revisions since they depend on the set (i.e. the mental state a person brings to the experience) and setting (i.e. the physical and social environment during the experience) of a psychedelic experience. Since the therapist and the therapeutic setting can substantially contribute to the set and setting, they can exert influence over the patient to an extent that is not present in other therapeutic interventions.*
Preparatory sessions	Preparatory sessions help the patient to get familiar with the therapeutic setting and the therapist. This way, the patient can gain an impression of how comfortable they feel in the therapeutic setting and whether they want to expose themselves to the vulnerable state coming with a psychedelic session. While preparatory sessions are standard in research settings, their number varies. Regarding the two phase-2 studies conducted so far, Carhart Harris et al. [19] only had one preparatory session, whereas Goodwin et al. [9] had at least three preparatory sessions (as a side note, the state of Oregon requires one preparatory session [91]). The latter study's stronger focus on preparatory sessions is desirable from a vulnerability perspective (but might also limit access to PAT due to higher costs, see [92]). Besides, more investment into preparing patients for the psychedelic experience should facilitate the building of a sound set and setting, promoting therapeutic effects [cf. 34].
First psychedelic session with lower dosage	Administering a lower-than-standard dosage offers a direct way to decrease the enhanced vulnerability coming with psychedelics: it reduces the effects of psychedelics, making bottom-up input less influential and high-level top-down predictions less revisable (but therapeutic effects also smaller). This measure could be implemented as follows: The first psychedelic session involves half of the standard dosage. After that first session, patients can then decide whether they want to continue with the full dosage. Beside reducing vulnerability, such a two-step procedure has another advantage: Patients get a first impression of what a (mild) psychedelic experience is like, which helps them to anticipate what a full-dosage psychedelic experience will be like. This should reduce epistemic inaccessibility in the informed consent process stemming from inexperience with psychedelics.
Specific training and oversight of	Psychedelic therapists need specific training emphasizing patients' enhanced vulnerability in PAT and strict oversight to minimize malpractice cases. For example, the state of Oregon has predetermined training curriculum modules such as 'awareness of increased

psychedelic therapists	vulnerability associated with altered states of consciousness' and 'set and setting' [91]. Moreover, Oregon's facilitator code of ethics highlights clients suggestibility and vulnerability *during and after* a psychedelic session and demands facilitators to provide as minimal directive support as possible [93]. The latter should reduce unintended exploitation of clients' vulnerability. Regarding oversight, Oregon carefully screens applicants of the psilocybin training and psychedelic facilitators must keep record of their services. But it is unclear whether these control mechanisms sufficiently reduce malpractice cases [cf. 92]. Stricter oversight for example in the form of mandatory supervision and/or regular inspections seem advisable.

4 CONCLUSION

The REBUS hypothesis provides an explanatory approach for psychedelic's therapeutic mechanism: under the influence of psychedelics, the brain's high-level predictions become revisable through the bottom-up sensory input. This mechanism is ethically relevant as it puts patients in a vulnerable and uncontrollable state where the influence of the therapist increases; a state that is not present in other therapeutic interventions to such extent. While this anarchic brain state makes large therapeutic effects possible, it also opens the door for malpractice as for example the Swiss case of the psychiatrist Samuel Widmer shows. Therefore, patients in current research settings and starting mainstream medical settings need to be informed about the psychedelics' mechanisms, their implications, and security measures to give well-informed consent to the treatment.

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