Psychology of Consciousness: Theory, Research, and Practice

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A Nondirective Physical and Psychological Support Protocol for Inhaled *N*,*N*-Dimethyltryptamine (DMT): A Qualitative Evaluation of Safety, Comfort, and Integration in a Clinical Setting

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Psychedelic-assisted psychotherapy has demonstrated effectiveness in treating depression and posttraumatic stress disorder, but its resource-intensive structure limits scalability. *N*,*N*-Dimethyltryptamine (DMT), with its rapid onset, short duration, and intense effects, offers potential for more time-efficient interventions but requires specialized support to ensure safety and comfort. This open-label, dose-escalation study, registered on https://clinicaltrials.gov (NCT05573568), evaluated a nondirective clinical support protocol for administering inhaled DMT to 27 healthy volunteers with previous DMT experience. The protocol included one preparatory session, a safety dose (5–15 mg) followed by a full dose (20–60 mg) on the same day, and four integration sessions—two on the dosing day, one the next day, and one 14 days later. DMT was administered via a medical-grade vaporizer. Integration tools included verbal debriefing, psychometric questionnaires, and, optionally, mandala drawing creation. Semistructured interviews conducted 28 days after dosing were thematically analyzed to assess participants' perceptions of safety, comfort, and integration. Four core themes emerged: dosage, setting, safety, and set-related aspects and integration. Participants emphasized the importance of preparatory work, a calming physical environment, consensual therapeutic touch, and symbolic tools such as mandalas to foster safety and emotional processing. Inhalation was generally well tolerated, and the brief yet immersive DMT experience was considered manageable within the protocol. This study introduces a feasible, scalable, and ethically grounded support protocol for inhaled DMT administration. By combining symbolic, psychological, and somatic strategies without in-session psychotherapy, it offers a viable alternative to resource-intensive psychedelic-assisted psychotherapy models and may guide future research and public health protocols.

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The data that support the findings of this study are available from Draulio B Araujo, upon reasonable request. Due to ethical and privacy considerations involving sensitive clinical and psychological data, the data set is not publicly available. Analytic methods and study materials can also be provided upon reasonable request to Draulio B Araujo. The study is part of a Phase I clinical trial, serving as a preparatory stage for a subsequent Phase II clinical trial involving individuals with treatment-resistant depression. The protocol was approved by the Research Ethics Committee of the Onofre Lopes University

continued

Keywords: *N,N*-Dimethyltryptamine, qualitative analysis, clinical protocol, psychedelic preparation, psychedelic integration

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Psychedelic compounds have reemerged in clinical research due to their potential to rapidly alleviate symptoms in mental health conditions such as treatment-resistant depression (Falchi-Carvalho, Barros, et al., 2025), posttraumatic stress disorder (Averill & Abdallah, 2022), and anxiety (Davis et al., 2020). *N,N*-Dimethyltryptamine (DMT) stands out for its unique pharmacological profile (Chaves et al., 2024). When administered via inhalation, DMT induces an intensely immersive but short-lived altered state of consciousness, typically lasting less than 20 min (Lawrence et al., 2022).

Naturally occurring in plants, animals, and in trace amounts in the human body (Barker, 2018), DMT is also the primary psychoactive component of ayahuasca, a traditional Indigenous Amazonian brew used ceremonially for centuries and often prepared from two different Amazonian plants (Labate et al., 2008; Ruffell et al., 2023). In modern contexts, its subjective effects are often described as profound, visual, and ineffable, marked by ego dissolution and a sense of breakthrough into alternate dimensions (Sanders et al., 2024; Shanon, 2003).

Beyond these phenomenological features, ayahuasca has shown therapeutic promise in several psychiatric conditions, particularly in depression, where both naturalistic and clinical studies suggest rapid and significant reductions in depressive symptoms following a single administration (Maia et al., 2023; Palhano-Fontes et al., 2019; Sanches et al., 2016). These antidepressant effects appear within hours and may persist for days or weeks, even in individuals previously unresponsive to conventional treatments (Palhano-Fontes et al., 2021).

The isolated administration of DMT in clinical settings has demonstrated promising therapeutic potential, mainly due to its unique pharmacodynamic profile characterized by a rapid-onset, intense phenomenological effects and short duration of action (Carbonaro & Gatch, 2016). These properties allow for brief sessions with minimal logistical burden and greater feasibility for implementation in controlled clinical environments. Evidence from previous studies using DMT via intravenous (D'Souza et al., 2022; Vogt et al., 2023) and intramuscular (Kaplan et al., 1974) routes supports the pharmacological safety

Hospital, Federal University of Rio Grande do Norte, Brazil (No. 45.532.421.0.0000.5292) and registered on https://clinicaltrials.gov (NCT05573568). All procedures followed established safety standards for psychedelic studies, Good Clinical Practice guidelines, and the principles of the World Medical Association's Declaration of Helsinki. A total of 27 healthy adults (Mean age = 30 years), all with previous experience with *N,N*-dimethyltryptamine (including ayahuasca), participated in the study. Eligibility was assessed during a psychiatric screening conducted by a psychiatrist experienced in psychedelic research. Full exclusion criteria are available in the Supplemental Material. All participants provided written informed consent, obtained individually by the psychiatrist on the day of screening, prior to inclusion in the study. The authors have no potential conflicts of interest to declare with respect to the research, authorship, and/or publication of this article.

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The authors thank Raphael Egel for composing the music used in the study, Kaike Thiê da Costa Gonçalves and Scarlett O'Hara Gabriela Medeiros Gonçalves Pereira for their help in the clinical and psychiatric monitoring, and Sérgio Ruschi for the chemical analysis of the substance.

The study's clinical team consisted of Marcelo Falchi-Carvalho, Handersson Barros, Sophie Laborde, Flávia Arichelle, and Aline Assunção. Marcelo Falchi-Carvalho was responsible for participant screening, administered the substance, and served as the project's lead psychiatrist. Handersson Barros and Sophie Laborde provided psychological support during the clinical phases, while Flávia Arichelle and Aline Assunção contributed to nursing care. The necessary authorizations were obtained by Draulio B. Araujo, Fernanda Palhano-Fontes, and Emerson Arcoverde. Data acquisition was performed by Lucas Maia. Natan Silva-Costa, Raissa Almeida, Raynara Bolcont, and José Costa-Macedo collaborated as research assistants. The protocols were structured with contributions from Handersson Barros, Draulio B. Araujo, Lucas Maia, Marcelo Falchi-Carvalho, Isabel Wießner, Fernanda Palhano-Fontes, Sophie Laborde, Geissy Lima-Araujo, Raynara Bolcont, and Sam Tulman. Data analysis and article writing were conducted by Handersson Barros, Draulio B. Araujo, and Lucas Maia.

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of the substance. However, these studies have focused primarily on pharmacokinetic characterization without incorporating structured stages of preparation, experience support, and psychological integration, which are now considered fundamental to enhance therapeutic outcomes and mitigate risks in clinical research.

By contrast, some psychedelic-assisted psychotherapy (PAP) models integrate structured psychotherapy during the acute drug session (Mithoefer et al., 2011). It is important to recognize, however, that PAP does not represent a homogeneous or unitary intervention but rather encompasses a heterogeneous set of practices, theoretical orientations, and session structures. Unlike lysergic acid diethylamide, psilocybin, or 3,4-methylenedioxymethamphetamine, which require several hours of therapeutic engagement, DMT's rapid onset and brief effect window challenge prevalent models of PAP. These models, while effective, are often labor intensive and costly, requiring extensive preparatory work, multihour synchronous psychotherapy sessions, and multiple trained therapists (Marseille et al., 2022; Stanicic et al., 2024).

By contrast, DMT's properties allow for more flexible and time-efficient protocols. However, the intensity of the experience imposes careful psychological preparation, environmental containment, and integration strategies, even in the absence of formal psychotherapy during dosing (Bender et al., 2025). In this context, support protocols focusing on safety, comfort, and symbolic integration, rather than real-time therapeutic intervention, are especially relevant (Ramaekers et al., 2025). In terms of the acute-session stance, the protocol aligns with contemporary supportive and nondirective models commonly employed in psilocybin and lysergic acid diethylamide trials, with its novelty residing in the adaptation of this stance to DMT's ultrarapid pharmacokinetics and stepped dosing regimen.

Recent clinical studies have begun to explore the safety and potential therapeutic effects of vaporized DMT as part of physical and psychological support protocols. A Phase I dose-escalation trial in healthy volunteers demonstrated that inhaled DMT is safe, well tolerated, and capable of inducing dose-dependent increases in intensity and emotional valence, without significant physiological or biochemical adverse effects (Falchi-Carvalho et al., 2024). Building on these findings, a subsequent open-label Phase 2a study with patients suffering from treatment-resistant depression reported rapid and sustained reductions in depressive symptoms following a single session of vaporized DMT, with 85.71% of participants responding by Day 7 and 57.14% maintaining remission at 1 month (Falchi-Carvalho, Palhano-Fontes, et al., 2025).

The literature reveals substantial variability in the therapeutic structures employed across psychedelic clinical trials, including differences in the duration and intensity of preparation and integration procedures, the therapeutic stance during the acute experience, the number and timing of sessions, and the clinical populations studied (Florineth et al., 2026). This heterogeneity largely reflects ongoing efforts to adapt psychedelic intervention frameworks to the action of each substance. In the case of DMT, characterized by rapid onset, high intensity, and short duration of action, a condensed and efficient support model is required.

The protocol presented in this study aligns with established PAP models, emphasizing the creation of a safe environment, the importance of set and setting, and the inclusion of structured preparation and integration steps (Brennan et al., 2023). However, it differs in terms of the number, duration, and clinical management of sessions, proposing a more flexible format specifically tailored to the unique pharmacodynamic properties of DMT, particularly its intense effects and short duration of action.

Another notable distinction from the classic PAP model is that, while the latter typically involves multiple therapists, most commonly a dyad consisting of a male and female therapist (Phelps, 2017), this protocol relies on the support of a single psychologist who accompanies the participant during preparation, dosing, and integration sessions. This approach simplifies logistics and reduces costs while maintaining the necessary standards of safety and support. Rather than requiring hours of synchronous psychotherapy during the acute effects of the substance, the protocol prioritizes supportive strategies that promote safety and comfort during the nonordinary state of consciousness. Thus, the protocol seeks to offer a more cost-effective alternative, potentially scalable to public health systems, and culturally adaptable while upholding the ethical principles of care, safety, and good clinical practices in research and interventions involving psychedelics.

Classic and contemporary research has emphasized the importance of set and setting, the individual's mindset, and the physical, social, and symbolic environment in shaping psychedelic experiences (Hartogsohn, 2017; Pontual et al., 2022). Supportive environments and attuned facilitators

can reduce anxiety and foster a sense of trust, especially in fast-acting psychedelic experiences wherein participants have limited cognitive control (Golden et al., 2022). In therapeutic contexts, the concept of the "matrix," which refers to the cultural and symbolic relationships within which substance use is embedded, also emerges as an extrapharmacological component that can influence clinical outcomes because it shapes the processes of meaning-making and subjectivation of these experiences (Eisner, 1997).

In this context, recent guidelines for psychedelic clinical trials reinforce the importance of rigorously reporting and structuring the extrapharmacological components involved in the intervention (Pronovost-Morgan et al., 2025). The international consensus, the Reporting of Setting in Psychedelic Clinical Trials, proposes guidelines consisting of 30 items organized into four main domains: physical environment, dosing session procedures, therapeutic framework and protocol, and subjective experiences. Systematic adoption of these guidelines aims not only to standardize scientific reporting but also to ensure optimal conditions of safety, comfort, and good clinical practice, thereby contributing to the efficacy and reproducibility of psychedelic interventions. The table with the recommended items, as per these guidelines and met in this study, is available in the Supplemental Material.

Another essential element in psychedelic practices is integration, understood as the process of building bridges between the psychedelic experience and everyday life through the elaboration and cultivation of meanings about what was experienced during the nonordinary state of consciousness (Earleywine et al., 2022). In the case of DMT, this process assumes particular importance, as its experiences are often difficult to articulate verbally, containing nonlinear, imagistic, or ineffable content. Therefore, nonverbal methods such as mandala drawing can provide support for reflection and emotional processing.

A mandala is a centered pattern image, usually circular, composed of smaller elements arranged symmetrically around a central point, and within Jungian psychology, it is understood as a symbolic space for organizing inner experience and restoring psychic balance (Jung, 1964). This understanding was later embraced in Brazil by figures such as the psychiatrist Nise da Silveira, who incorporated mandalas into therapeutic contexts as a means of accessing and integrating subjective experience (Da Silveira, 1981). This strategy is particularly well suited to the DMT state, which frequently generates intense visuals and deep emotional resonance in a short period of time (Barros et al., 2025). In the present study, integration focused on the verbal expression and elaboration of the experience, but the optional creation of a mandala was also offered as a complementary tool for symbolic integration, aimed at elaborating elements that escape verbalization.

Additionally, somatic tools such as consensual therapeutic touch have emerged as valuable additions to psychedelic protocols (Ham et al., 2025). These body-based strategies support emotional regulation and grounding, especially when verbal interaction is not feasible (Luoma & LeJeune, 2025). For fast-acting psychedelics like DMT, these techniques can support self-regulation during the experience and reinforce a sense of safety during peak effects (Neitzke-Spruill et al., 2025).

Despite DMT's promise and growing evidence of its safety and efficacy, there is a lack of published clinical protocols that integrate psychological, physical, symbolic, and somatic support (Cavarra et al., 2022). Most studies focus on pharmacological outcomes or neurobiological markers, leaving a gap in applied frameworks for ethical, replicable administration in research and clinical settings (Van Elk & Fried, 2023).

The present study addresses this gap by presenting and qualitatively evaluating a structured clinical support protocol for administering inhaled DMT. The protocol includes preparatory and integration sessions, physical and emotional support during dosing, optional somatic grounding tools, and symbolic integration through mandala drawing. Rather than targeting therapeutic outcomes, the study focuses on participants' subjective experiences of safety, comfort, and support throughout the protocol. Through thematic analysis of postsession interviews, we examine which protocol elements were most effective from the participants' perspectives. We also consider how such structures might inform future DMT research, particularly in contexts that require scalable, culturally adaptable, and ethically grounded models for psychedelic care.

Method

This open-label, fixed-sequence, dose-escalation study aimed to evaluate the clinical protocol of physical and psychological support for DMT (99.0% pure) intervention in a nonclinical population. The

evaluation was conducted through qualitative analysis of participants' discourse. The study was conducted as a preparatory stage for a subsequent phase II clinical trial involving individuals with treatment-resistant depression. The protocol was approved by the Research Ethics Committee of the Onofre Lopes University Hospital, Federal University of Rio Grande do Norte (No. 45.532 .421.0.0000.5292), and registered on https://clinicaltrials.gov (NCT05573568).

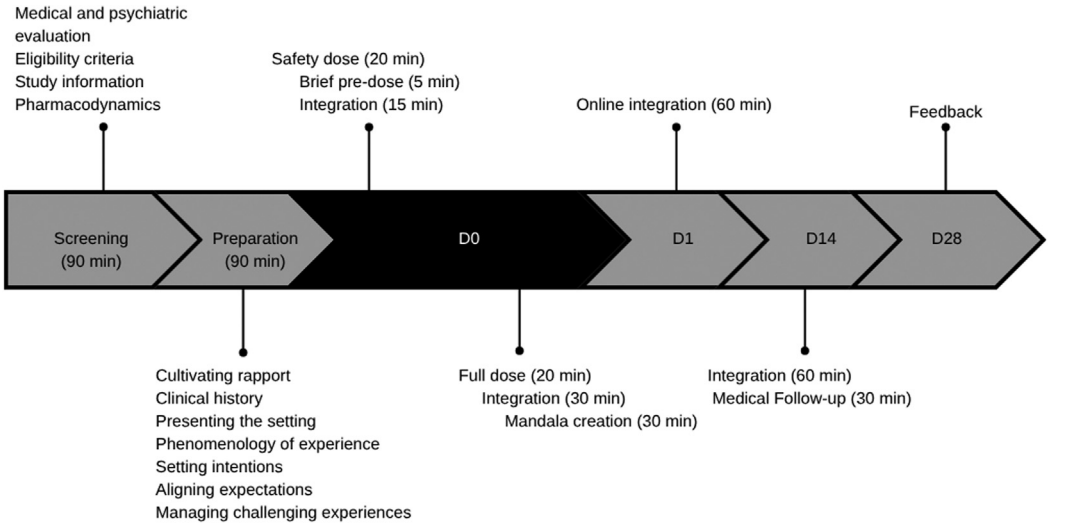
Study Design

The protocol involved multiple components: a psychiatric screening (90 min) conducted during the week prior to the dosing session, one preparatory session with a psychologist in the dosing room (lasting 90 min) held days before dosing, a brief predose check-in (5 min), two dosing sessions on the same day (a safety dose of 5–15 mg of DMT and, 2 hr later, a full dose of 20–60 mg of DMT), and four integration sessions: two conducted in person shortly after the reduction of effects—the first lasting up to 15 min, following the safety dose, and the second lasting up to 60 min, after the full dose, with the optional creation of a mandala. The remaining sessions took place 1 day after dosing, held online, and 14 days later, conducted in person, both lasting up to 60 min. After the final in-person integration session, a medical follow-up conducted by the psychiatrist takes place, marking the conclusion of the clinical phase of the protocol. All sessions were conducted at the Clinical Psychedelic Research Unit at Onofre Lopes University Hospital in Natal, the capital of Rio Grande do Norte, Northeastern Brazil, supported by a multidisciplinary team. The clinical safety outcomes of this study have been reported elsewhere (Falchi-Carvalho et al., 2024). Figure 1 presents the study protocol design, including the screening and preparation stages, the administration of two doses of DMT on day zero (D0), and the subsequent integration sessions, followed by medical follow-up and a feedback interview at D28. This schematic representation provides an overview of the temporal sequence and the main components of the clinical design.

Participants

Twenty-seven healthy adults, of whom 25 (F:12; M:13) completed the inhalation, with a mean age of 30 years (30.3 ± 6.5; 21–51) and previous experience with DMT (including ayahuasca), were recruited through online advertisements and word of mouth. Eligibility was determined during a

Figure 1
Design of the Clinical Protocol for Inhaled Dimethyltryptamine



Note. After screening and preparation, participants received two doses of *N,N*-dimethyltryptamine on day zero (D0, dosing day) and took part in online (D1, next day) and in-person (D14, 14 days later) integration sessions, followed by medical follow-up. Twenty-eight days after dosing (D28, 28 days later), a feedback interview was conducted.

psychiatric screening conducted by a psychiatrist with experience in psychedelic research. Exclusion criteria included psychiatric or medical conditions that contraindicated the use of DMT; the complete eligibility criteria are provided in the Supplemental Material. All participants provided written informed consent collected by the psychiatrist. Demographic details are available in the Supplemental Material.

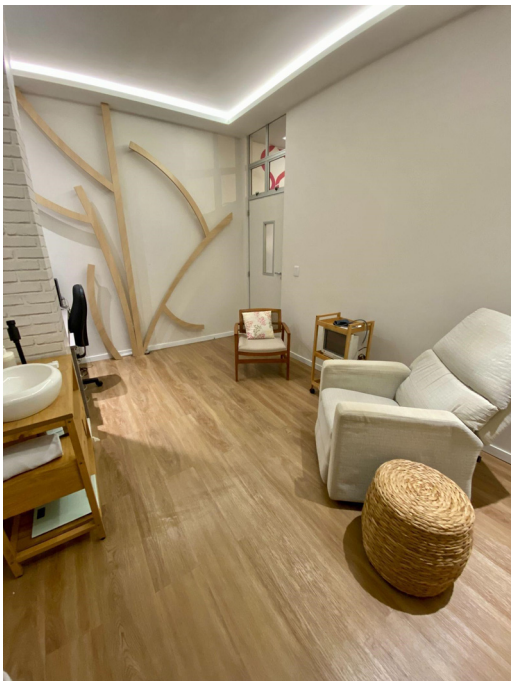
Procedure

All procedures followed established safety standards for psychedelic studies (Johnson et al., 2008), Good Clinical Practice guidelines, and the World Medical Association's Declaration of Helsinki and were guided by structured checklists designed to ensure protocol fidelity and consistency across sessions. Sessions were conducted in a dedicated clinical room specifically designed for psychedelic research, featuring a natural color palette, wood-toned flooring, adjustable lighting and temperature, and a layout optimized for comfort and monitoring. The space incorporated biophilic design elements, including wall structures resembling branches or roots, evoking a symbolic connection to nature. The dosing room was equipped with a reclinable armchair for the participant, additional seating for the support team, medical monitoring equipment, a computer, a sink, functional light wood furniture, and a separate waiting area. Figure 2 presents the physical environment in which the in-person stages of the study were conducted, highlighting a carefully arranged, comfortable, and aesthetically supportive setting designed to promote safety and comfort.

Predosing Sessions

The screening session included an initial interaction with the psychiatrist to establish rapport, assess general health, verify eligibility criteria, clarify expectations, and provide information about the study and the pharmacodynamics of the"substance. The preparatory phase, conducted by the same psychologist who accompanies the participant during the dosing and integration sessions, focused on reducing anxiety, familiarizing participants with the environment and equipment, cultivation of the therapeutic alliance, gathering clinical history, setting intentions, aligning expectations, discussing previous experiences with psychedelics, providing information about the phenomenology of the experience and clinical procedures, addressing questions and concerns, as well as training for managing challenging experiences. Strategies included intention setting, psychoeducation, and guided reflection through open-ended questions to explore relevant personal and psychological themes.

Figure 2
Physical Environment Where the In-Person Stages of the Study Were Conducted



Note. See the online article for the color version of this figure.

Breathwork techniques and consensual therapeutic touch were introduced during the preparation phase. Touch was defined as a light, nonfrictional hand-holding gesture, used only with explicit mutual consent. Training for navigating challenging experiences followed a structured protocol, available in the Supplemental Material, and concluded with guided practice of the inhalation technique.

Dosing Sessions

Each participant received two doses of vaporized DMT on the same day, using one of five dose regimens (e.g., 5/20 mg, 7.5/30 mg, up to 15/60 mg). DMT was vaporized in a medical-grade vaporizer (Volcano Medic 2, Storz & Bickel GmbH & Co, Tübingen, Germany). The full dose was withheld if

adverse physiological changes occurred after the safety dose. During the substance's effect, participants remained comfortably reclined in a reclining armchair, wearing headphones to listen to tracks specifically designed for the study.[1] They were previously instructed to keep their eyes closed during the experience and to attend to their internal perceptions such as thoughts and emotions. No eyeshade mask was used. A multidisciplinary team supervised the dosing, including the psychiatrist experienced in psychedelic research who administered the substance and was seated in front of the participant. The psychologist sat beside the participant, while the nurse was seated on the other side. The neuroscientist and a professional in training on the protocol positioned themselves peripherally. Physiological data (blood pressure, heart rate, temperature) and electroencephalography data were recorded, and saliva, blood, and respiratory samples were collected. Acute subjective effects were assessed using the Hallucinogen Rating Scale. Data collections were conducted on the same day as the dosing session.

Integration Sessions

Immediately after the safety dose, a 15-min integration session was conducted. After this, scales were completed, vital signs were recorded, and biological material was collected. Following a clinical evaluation by the psychiatrist, and in the absence of any contraindications, the full dose was administered, followed by a 60-min integration session consisting of a verbal debriefing (30 min) and, optionally, the creation of a mandala drawing (30 min). Integration was led by the psychologist, with support from the psychiatrist. The integrative process continued with an online session the following day (D1) and an in-person session on Day 14 (D14), both lasting up to 60 min. The clinical phase of the protocol concluded with a medical follow-up (D14), lasting up to 30 min.

Integration sessions followed a semistructured neurophenomenological script, progressing from descriptive recall to more profound personal meaning-making (Petitmengin, 2006). This approach was applied progressively, with increasing complexity both within each session and across the different integration sessions. The process began with open-ended questions aimed at expressing the immediate experience, followed by detailed description, body scanning, and emotional and reflective elaboration and eventually reached more complex levels of symbolic meaning-making and the cultivation of existential sense. The mandala activity, guided by the psychologist with expertise in transpersonal psychology and training in harm reduction, provided a symbolic medium for nonverbal expression. Participants were given a 45×45 cm white sheet with a central circle and 50 crayons. The resulting artwork depicted the psychedelic experience.

Follow-Ups

Two hours after the second dose, the participants underwent a medical evaluation conducted by the psychiatrist. Once deemed clinically stable, they were optionally served a carefully prepared lunch, adapted to individual dietary restrictions, after which they were discharged in the presence of a designated companion.

Follow-up assessments were conducted on Days 1, 2, 7, 14, and 28 using standardized instruments. The psychometric scales used in the study played distinct roles in assessing subjective and functional aspects of the participants. The World Health Organization Quality of Life assessed quality of life across different domains; the State-Trait Anxiety Inventory measured anxiety levels; the Satisfaction With Life Scale investigated the overall degree of life satisfaction; the Positive and Negative Affect Schedule examined the presence of positive and negative affects; the Epworth Sleepiness Scale evaluated daytime sleepiness; and the Hallucinogen Rating Scale was used to measure the acute subjective effects of the psychedelic experience, alongside clinical interviews and adverse event monitoring conducted by the psychologist and psychiatrist.

Thematic Analysis

This study applied thematic analysis to semi-structured online feedback interviews conducted 28 days after the dosing session (D28). Thematic analysis is one of the most widely used qualitative methods in health research, offering a flexible yet rigorous approach to identifying, analyzing, and interpreting patterns or themes within a data set

[1] The music was composed by the musician Raphael Egel and comprised elements of electronic, harmonic, ambient, and a curated selection of calming instrumental music to guide the experience and create a climate of safety and relaxation (https://www.raphael-egel.com).

(Braun & Clarke, 2006; Nowell et al., 2017). Interviews were guided by open-ended questions designed to explore participants' subjective experiences of the clinical protocol, focusing on perceptions of safety, comfort, and support throughout the various phases, from screening to the final integration session. These interviews were conducted by a researcher who had not previously interacted with the participants. The complete interview script is provided in the Supplemental Material.

The first step involved transcription of the interview recordings. This began with floating listening, a technique in which the researcher listens to the tapes without taking notes to gain a general impression of the narrative (Terry et al., 2017). A second round of listening was conducted with active attention to identify relevant excerpts and initial meaning units. A professional academic transcription service completed a full verbatim transcription.

Following transcription, the process of generating codes began (Maguire & Delahunt, 2017). Codes are labels assigned to specific excerpts in the text that represent emerging concepts, such as mandala or touch. These meaning units reflect participants' experiences and interpretations and are used to organize the data systematically. Each excerpt could be associated with one or multiple codes, depending on its content and relevance.

Once the initial codes were generated, they were grouped into broader themes. Themes capture more abstract, overarching patterns in the data, emerging inductively from repeated engagement with the coded material (Naeem et al., 2023). For example, the theme "integration" comprised several codes, including mandala, integration strategies, and reflection. Themes were not defined solely by frequency but also by relevance to the research questions, depth of insight, and their capacity to capture meaningful dimensions of the participants' experiences.

The themes underwent a process of refinement through peer review and discussion among three coresearchers: the lead graduate researcher (Handersson Barros), his advisor (Draulio B. Araujo), and his coadvisor (Lucas Maia). This triangulation process aimed to improve interpretative rigor by reducing individual biases (Lauri, 2011). Through collaborative review, the themes were adjusted to eliminate redundancies, clarify boundaries, and ensure that each theme accurately represented the underlying data.

The final themes were organized into four overarching categories, each composed of several subthemes aligned with the most relevant codes. Dedoose (https://www.dedoose.com), a multiplatform application that analyzes and processes qualitative and mixed-methods research texts, was used to support the thematic grouping process. Participants' perceptions of safety and comfort throughout the intervention were central to the analysis. Thematic connections were identified, and their implications were explored in light of the study's objectives. The results are presented in detail in the following section, with illustrative quotes used to support and contextualize each theme and subtheme. Each quote is labeled with an alphanumeric code (e.g., S18) that corresponds to the anonymous identification of the participant. Additional citations are available as Supplemental Material.

Transparency and Openness

The data that support the findings of this study are available from the corresponding author, Draulio B. Araujo, upon reasonable request. Due to ethical and privacy considerations involving sensitive clinical and psychological data, the data set is not publicly available. Analytic methods and study materials can also be provided upon reasonable request to the corresponding author.

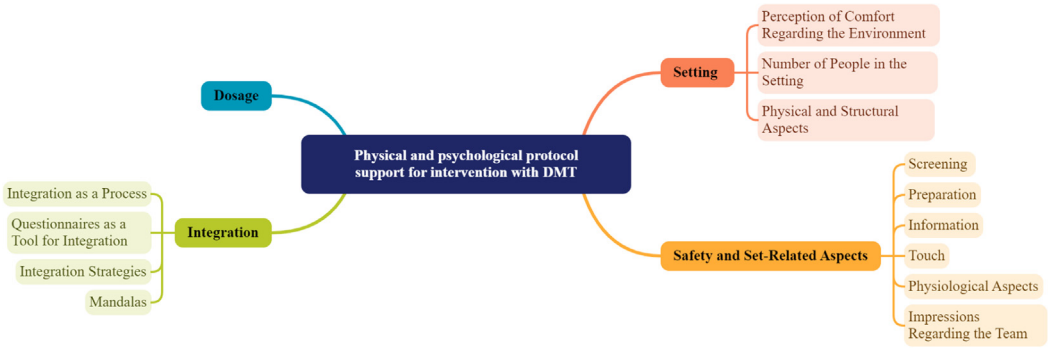
Results

Thematic analysis yielded 14 final codes, which were refined through iterative review of participants' narratives. These codes were then organized into four overarching themes that capture the core dimensions of participants' experiences: (a) dosing, (b) setting, (c) safety and set-related aspects, and (d) integration. Figure 3 displays the thematic map developed from this analysis, illustrating the four primary themes and their corresponding codes presented as subthemes. Figure 3 displays the thematic map developed from this analysis, illustrating the four main themes and their respective codes presented as subthemes.

Dosing

This theme addresses the process of DMT administration during the dosing session. The goal of this session is to achieve a meaningful psychedelic state through carefully calculated and supervised doses, aiming to balance safety with the potential for therapeutic benefit. In

Figure 3
Thematic Map of the Qualitative Analysis Results



Note. Thematic map presenting the final results of the qualitative analysis, including the main themes and their respective codes derived from participant interviews conducted 28 days after the dosing session. DMT = *N,N*-dimethyltryptamine. See the online article for the color version of this figure.

this case, the theme description is synonymous with the code. The code specifically refers to the method of substance administration using a tabletop vaporizer.

Participants described their experiences with this method, noting differences based on prior familiarity with inhaling vaporized substances. For some, the process was intuitive and well-tolerated; for others, it required adjustment. Nonetheless, vaporization was generally perceived as a noninvasive, comfortable, and effective route of administration in the clinical context:

> It was different for me because I'd never inhaled by vaporization before. … I thought the three seconds went by very quickly, and the effect was actually almost immediate. Before I lay down, I was already feeling the effect. … Maybe with the inhalation method, the way it was done, vaporized, it's the method where the effect comes faster, unlike the other methods I've tried. (S18)

This account illustrates the rapid onset of effects and the participant's recognition of vaporization as an efficient administration method. While inhalation may not be effortless for all individuals, especially those unfamiliar with vaporized delivery, using the Volcano Medic appeared to offer a standardized and clinically appropriate solution.

Setting

This theme reflects how participants experienced the physical and interpersonal environment during the dosing sessions. It includes three distinct codes: perception of comfort regarding the environment, number of people in the setting, and physical and structural aspects. Collectively, these codes capture how the design of the setting and the presence of the research team contributed to feelings of safety, calm, and familiarity throughout the experience.

Perception of Comfort Regarding the Environment

Participants frequently expressed a sense of ease and emotional security in the dosing environment. Even though the sessions took place in a hospital, careful attention to aesthetic and symbolic elements, such as lighting, natural textures, and meaningful visual cues, helped transform the clinical space into one that felt tranquil and inviting:

> The environment itself is very welcoming, as I said, when I entered the waiting room, it felt like I was at home. It didn't feel like I was in a hospital about to have a DMT experience. So, it felt like I was in a familiar, pleasant environment. (S13)

This account suggests that the environment played a vital role in establishing psychological safety, a key component for therapeutic psychedelic experiences.

Number of People in the Setting

Participants also commented on the number of professionals present and their movement within the room. The presence of a multidisciplinary team was generally perceived as well-balanced, providing support and reassurance without becoming intrusive. Prior briefing

about who would be in the room and their roles helped reduce anxiety and avoid feelings of unpredictability:

> There was no discomfort with the number of people, I didn't find the room crowded, in fact, I felt very safe. … I think I had a spike in blood pressure and a very rapid heartbeat during the second dosage, and I thought exactly this: when there was a spark of anxiety, I just reminded myself, "I am in the best possible place for anything to happen." So, it was very calm, the number of people was ideal; if there had been more people, it might have been problematic, but this number was perfect. (S11)

This account emphasizes that the right balance between presence and discretion can enhance participants' sense of security during nonordinary states of consciousness.

Physical and Structural Aspects

The third code captures how participants experienced the room's layout, lighting, and temperature. Elements such as soft lighting, neutral colors, and adjustable temperature contributed to physical comfort, especially for participants more sensitive to sensory input during the psychedelic state:

> I liked the lighting; I thought it was really nice, just right, and it didn't hurt my eyes. When I come into contact with these substances, I become very sensitive to brightness. I imagined that this would bother me, and the environment would be too bright there, but I found it to be quite cozy and comfortable. (S03)

Participants were previously instructed to keep their eyes closed during the experience; no eyeshade mask was used. They also valued the size and arrangement of the room, reporting that the main room and the anteroom felt appropriately designed for the experience.

Safety and Set-Related Aspects

This theme gathers participant reflections on elements contributing to a sense of security, trust, and emotional readiness throughout the protocol. It comprises six interrelated codes: screening, preparation, information, touch, physiological aspects, and impressions regarding the team.

Screening

Participants consistently emphasized the value of the medical screening session as more than a bureaucratic or clinical filter. This initial contact with the psychiatrist, conducted in the exact location as the dosing, was experienced as an essential step in building trust, clarifying eligibility, and reducing anticipatory anxiety:

> The physical monitoring with the psychiatrist and everything, I also found super important, because we know it's not for everyone. There are also some criteria for whether you can use these substances or not. So, I think this screening gave me a sense of security that it was indeed happening. (S17)

Rather than merely a technical procedure, screening helped establish an initial layer of safety and confidence, supporting the participant's decision to proceed with the study.

Preparation

The preparation phase was facilitated by the psychologist and proved essential in fostering rapport, security, and emotional comfort. Participants developed greater clarity and reassurance about the process ahead through intention setting, expectation management, and discussion of possible challenges:

> It was essential to transmit security, I think they would be able to convey that well. And so, I already had knowledge of the experience, but the guidance on how to face the difficult moments of the experience was very important. (S22)

These sessions provided practical orientation and emotional support, allowing participants to enter the dosing session with reduced anxiety and a sense of trust in the process and the team.

Information

Participants highlighted the importance of receiving clear, detailed information throughout the study. The team's transparency and care in explaining procedures, equipment, and expectations were decisive factors in creating psychological safety:

> They were always indicating what they were doing and why, everything very neatly, so nothing was without my consent, so to speak. They always, in each process, explained why it was happening that way, so it was very smooth. (S07)

This transparent communication helped prevent confusion and surprise, reinforced participants' sense of agency, and enhanced their comfort within the protocol.

Touch

Participants recalled the optional use of therapeutic touch, prediscussed and consensual, as a significant gesture during emotionally intense moments. The simple act of holding a hand was described as grounding and supportive:

> I started feeling anguish, and the psychologist was by my side. In that moment of distress, I fed into that anguish, and it started transforming into something else, but I managed to take control. The psychologist was by my side, he saw the anguish showing on my face, and he held my hand, doing everything he had said he would do, like touching my hand if he noticed something like that. (S13)

This somatic presence provided nonverbal reassurance, reinforcing the coregulatory role of the therapeutic alliance during peak psychedelic states.

Physiological Aspects

While not central to most participants' narratives, some reported minor physiological discomforts, such as fatigue or basic bodily needs, which were managed without distress:

> I was also concerned about needing to pee at some important moment, but I went to the bathroom, and it was very smooth. (S05)

These accounts suggest that, though expected, physical needs can momentarily surface during altered states and should be anticipated in protocol design to ensure sustained comfort.

Impressions Regarding the Team

Participants repeatedly praised the clinical team's professionalism, attentiveness, and human presence. A key element highlighted was the team's technical expertise and personal or experiential understanding of psychedelic states:

> The fact that the psychologist also had contact with psychedelics is fundamental, I would highlight that. You need someone who really has. … I imagine all of you have a good background in this area, to grasp the nuances, and know what to ask. It was very smooth; I think it was productive. He managed to talk about things from the experience, but I also managed to talk about things from my personal context, the moment when this came into my life, and how those two moments interacted—the broader movement and the moment of the experience itself. (S11)

This sense of shared understanding, combined with warm and nonjudgmental support, helped participants feel deeply seen and cared for, amplifying the emotional resonance and depth of the experience.

Integration

This theme explores how participants reflected on and assimilated their experiences in the days and weeks following the dosing sessions. It includes four principal codes: integration as a process, questionnaires as a tool for integration, integration strategies, and mandalas.

Integration as a Process

Participants described the integration phase as essential for understanding and translating the DMT experience into meaningful personal insights. Conversations with therapists were particularly valued for bridging the clinical protocol and participants' inner worlds:

> I think this possibility, this help, I would say, with the therapist to integrate the experience—I found that very interesting, it really helped to give more meaning, you know? I already had some psychedelic experiences, but this integration work was very interesting, I thought it was the highlight of the experience, of the protocol as a whole. (S22)

These reflections show that integration extended beyond the formal structure of the study; participants viewed it as a deeply personal process that connected the research setting to their own lives and goals.

Questionnaires as a Tool for Integration

Though initially unexpected, the repeated completion of questionnaires was reported as helpful for reflection. Participants noted that the structured questions offered an opportunity to revisit and organize emotional and cognitive responses:

> The questionnaires help in the same sense—they also apply to what I was saying—they give you support so that you can build reasoning around the experience in a complete way. (S01)

This feedback suggests that psychometric instruments can be active in postsession integration and serving research aims, mainly when used alongside therapeutic support.

Integration Strategies

Participants also described various personal integration strategies beyond those provided by

the protocol. These included writing, meditation, body movement, and conversations with trusted individuals. Such practices were seen as essential to process the experience fully:

> Therapy or talking to people who were aware and understood what happens, who are open to discussing it. That's how it was. I wrote, on the same day I wrote a lot, I read, anyway, I meditated. I also integrated in other ways. (S17)

These accounts underscore that integration is not a one-size-fits-all process. Participants drew from personal habits and creative practices to elaborate on the meaning of their experience and apply it to their everyday lives.

Mandalas

The creation of a mandala drawing was offered after the second dosing session as an optional integration activity. All but one participant chose to engage in this activity. Participants described the process as intuitive, creative, and emotionally resonant, helping express the aspects of the experience that were difficult to verbalize:

> I thought it was really cool; I didn't expect to be offered to make a mandala. But it was interesting because, in a way, it elevated the DMT experience to a more spiritual level and the relationship of these mandalas, these symbols, with the issue of psychic development, personality development, individuation, from an analytical, Jungian perspective. I've been making mandalas for a while, so for me, it was really cool to talk a bit about them, about what they represented for me, how they emerged during the experience. I really liked it. (S23)

Figure 4 presents mandalas created by three participants during the integration session following the second administration of inhaled DMT, illustrating individual symbolic elaborations of the psychedelic experience and expressing emotionally condensed elements or aspects that are difficult to verbalize.

The symbolic and visual language of the mandala provided a way to access and express nonverbal insights. For some, it also evoked deeper layers of meaning, connecting the psychedelic experience to broader themes of everyday life.

Discussion

It is important to emphasize from the outset that the primary aim of this study was not to validate the protocol through between-group comparisons but rather to provide a systematic description and an in-depth analysis of the first-person therapeutic experience as lived by the participants. The scope of the present study was intentionally centered on participants' subjective experience, captured through qualitative methods, rather than on the assessment of physiological or biomedical safety outcomes; in this

Figure 4
Symbolic Mandala Expressions During Psychedelic Integration

Note. Mandalas created by three participants (S27, S19, and S23) during the integration session following the second dosing of inhaled *N,N*-dimethyltryptamine. Each drawing reflects individual symbolic elaborations of the psychedelic experience, expressing emotionally condensed or challenging to verbalize elements. These images illustrate the diversity of visual integration processes and highlight the mandala as a valuable expressive resource for meaning-making in nonordinary states of consciousness. See the online article for the color version of this figure.

context, safety-related data primarily refer to participants' own perceptions.

In this sense, the protocol presented advances an approach within the medical and psychiatric sciences that recognizes the epistemological value of direct subjective experience. In psychotherapeutic interventions, particularly those involving nonordinary states of consciousness, the patient's lived experience constitutes the core of the therapeutic process rather than a byproduct (Yaden & Griffiths, 2021). Accordingly, the evidence presented here is grounded in structured phenomenological data, recurrent patterns of self-report, and clinical coherence. Although between-group comparisons represent a well-established method for certain types of inference, they do not constitute the only legitimate pathway for the production of scientific evidence.

This study presents a clinical protocol for physical and psychological support for the administration of inhaled DMT that emphasizes comfort, safety, and integrative processes while offering a feasible alternative to the prevailing PAP paradigm. Unlike the extensive and resource-intensive structure of PAP, the present protocol proposes a condensed, nondirective model that preserves core therapeutic principles while enhancing scalability and applicability, particularly within public health systems.

A significant advantage of the proposed model lies in its reduced structural complexity and cost. The protocol consists of four in-person meetings and one online, prioritizing safety and psychological support over formal psychotherapy. This approach is particularly relevant when working with DMT, a fast-acting psychedelic whose intense effects often hinder coherent verbal communication during the peak of the experience (Timmermann et al., 2019). Unlike 3,4-methylenedioxymethamphetamine, which typically allows for dialogue and psychotherapeutic intervention during the session (Mithoefer, 2015), the DMT experience unfolds within minutes. It requires a support model emphasizing comfort, noninvasiveness, and postsession integration.

Overall, the central elements of the physical and psychological support protocol proposed here converge with components widely described in other models of psychedelic interventions, including those presented by Griffiths (Johnson et al., 2008), the clinical trials conducted by COMPASS (Goodwin et al., 2022), and 3,4-methylenedioxymethamphetamine studies (Mitchell et al., 2021). As in these protocols, the present model incorporates preparation, dosing, and postexperience integration sessions. However, it is distinguished by proposing a more condensed structure, with a reduced number of formal preparatory and integration sessions, while preserving essential therapeutic principles such as therapeutic alliance, intention setting, and expectation alignment.

Among its innovations is the implementation of two DMT sessions on the same day, consisting of an initial safety dose followed by a full dose after clinical evaluation, a strategy aimed at risk minimization and progressive familiarization with the nonordinary state of consciousness. The protocol also proposes that a single psychologist accompany the participant from the preparatory session through the final integration session, in contrast to the traditional therapeutic dyad model, typically composed of one male therapist and one female therapist (Phelps, 2017), seeking to promote continuity of the therapeutic relationship and greater operational feasibility. In addition, it incorporates the creation of mandalas as an expressive resource within the integration process, aiming to facilitate the symbolic integration of the experience.

Whereas earlier protocols often involve multiple extensive preparatory sessions and formal psychotherapeutic interventions during and after the experience, the present protocol emphasizes continuous clinical support, safety, comfort, and brief, focused integration processes, seeking to enhance feasibility, scalability, and potential implementation within public health systems without relinquishing elements considered fundamental for the safe and ethically responsible conduct of psychedelic interventions.

Another innovation of this clinical trial is the inhaled administration of DMT. Previous clinical studies with DMT alone have favored intravenous administration (Gallimore & Strassman, 2016; Strassman, 2001), which may contribute to participant discomfort. Trypanophobia, which affects over 60% of participants in clinical settings (Alsbrooks & Hoerauf, 2022), can significantly interfere with the subjective quality of psychedelic experiences, especially by modulating the participant's "set" or internal state before dosing. The inhaled route offers a noninvasive, more comfortable alternative and is easier to integrate into outpatient care models. Participants in this study confirmed that the absence of needles contributed to a greater sense of safety and reduced anticipatory anxiety, supporting findings from the broader literature linking physical and emotional comfort to psychological outcomes (Devenot et al., 2022).

Despite its advantages, inhalation also presented specific challenges. Some participants reported difficulties fully inhaling the vapor or experienced coughing during administration. However, these discomforts were transient and generally did not impact the overall experience. The two-step dosing design of the protocol, starting with a safety dose followed by a full dose, appeared to mitigate adverse effects and support participants' adaptation. This gradual approach is another innovation of the protocol.

Another strength of this study is its attention to duration and time efficiency. Compared with other psychedelics, DMT induces a rapid and robust experience that resolves within minutes to an hour, depending on the route of administration (Barker, 2022). This pharmacokinetic profile is particularly advantageous in public health settings, where the ability to conduct shorter, focused sessions without compromising intensity is logistically and economically significant. While intravenous administration may offer tighter dose control, the inhalation route used here achieved comparable experiential depth with less burden on staff and infrastructure.

The design of the physical setting was also critical in promoting psychological safety. Literature has long emphasized the importance of set and setting in shaping psychedelic outcomes (Hartogsohn, 2022; Leary et al., 1964). This study intentionally configured the clinical room to resemble a therapist's office rather than a hospital suite. Efforts included natural lighting, soft furnishings, and the absence of White coats among the psychology team, except where clinically required. Although a few participants still experienced surgical imagery during dosing, particularly during blood collection, these were interpreted as symbolic and did not negatively affect the overall session.

In terms of psychological preparation, the protocol included screening for psychiatric risk factors and a preparatory session focused on reducing anxiety, familiarizing participants with the environment and equipment, strengthening the therapeutic alliance, setting intentions, aligning expectations, and providing information about the phenomenology of the experience and clinical procedures. Training for managing challenging experiences was also included. These practices are consistent with established recommendations for preparatory sessions prior to psychedelic interventions (Villiger, 2025). The preparatory sessions also served as an opportunity to introduce somatic and symbolic support tools, such as breathing techniques, consensual touch, and the invitation for participants to bring comfort objects, such as amulets or items of personal symbolic value, helping them feel more equipped to navigate nonordinary states of consciousness. Participants often described this phase as essential for building rapport with the clinical team and reducing anticipatory anxiety.

The inclusion of touch as a therapeutic resource was also an essential element of the protocol. Touch functioned as a grounding mechanism during moments of emotional distress when used appropriately and with prior consent. This aligns with growing evidence supporting somatic interventions in psychedelic care (Back et al., 2024; Luoma et al., 2024; McNamee et al., 2023). Participants reported that simple gestures, such as consensually holding hands, provided a sense of connection and emotional anchoring. It is important to emphasize that touch was always discussed beforehand and applied with clinical sensitivity, reinforcing its role not as a standard intervention but as a supportive tool.

The integration process was the most meaningful component of the protocol, both in participants' subjective reports and in the broader conceptual framework of psychedelic care. Integration is widely recognized as essential for translating transient psychedelic insights into lasting psychological change (Bathje et al., 2022). This study's integration occurred on multiple levels: verbal debriefing, symbolic elaboration (through mandala drawing), and structured reflection via postsession questionnaires. This multimodal structure allowed participants to revisit and reframe their experience, promoting emotional processing and cognitive coherence.

The integration process adopted in this study, grounded in a neurophenomenological approach, represents a significant methodological advancement in the context of contemporary psychedelic research. Neurophenomenology proposes a dialogue between first-person accounts (subjective reports) and third-person data (neurobiological measures; Maturana & Varela, 1987), allowing for a more robust and multidimensional understanding of the subjective transformations reported after the psychedelic experience. This articulation between subjective and objective dimensions is particularly valuable in studies involving DMT. Previous work has often highlighted the difficulty of translating such experiences into clinically meaningful contexts (Millière, 2017). By

adopting neurophenomenology as an integrative framework, the present protocol helps mitigate this risk of discontinuity between experience and therapeutic application, offering tools for participants to transform intense symbolic and affective content into elements useful for self-reflection and psychological reorganization.

The use of mandalas as an integrative tool reflects both historical and clinical precedent. Rooted in analytical and transpersonal psychology (Grof et al., 2019; Jung, 1972), the mandala offers a symbolic container for nonverbal expression. In the context of DMT, where ineffability is a central feature (Barrett & Griffiths, 2018; Cott & Rock, 2008; Pahnke, 1963), participants reported that the mandala helped them externalize and reflect upon otherwise indescribable elements of their journey. The present study innovated by adopting a phenomenological, not interpretive, approach: Psychologists facilitated discussions without assigning symbolic meaning, allowing the volunteer's narrative to guide meaning-making. This aligns with the Brazilian tradition of art-based psychotherapy championed by Nise da Silveira (Da Silveira, 1992), who emphasized the autonomy of the individual's symbolic world in clinical expression.

Beyond artistic tools, the protocol also leveraged structured questionnaires for postsession reflection. Although primarily designed for data collection, participants noted that responding to these instruments helped clarify their thoughts and consolidate emerging insights. This dual role, scientific and therapeutic, highlights the potential of well-designed instruments as part of integrative practice (Frymann et al., 2022). Notably, the questionnaires offered participants a private, introspective space for articulating aspects of the experience that might not have surfaced during verbal sessions.

Participants also described using personal integration strategies, such as meditation, body movement, reflective journaling, and conversations with peers or therapists. These self-directed practices emphasize the individualized nature of integration and support the notion that long-term incorporation of psychedelic experiences is not confined to formal settings (Pilecki et al., 2021; Robinson et al., 2024). Without prescribing specific practices, the protocol's encouragement of self-reflection during the integration sessions appears to have created space for personal agency in the integrative process.

In addition to expanding access and preserving the subjective depth of the experience, the protocol helps mitigate risks frequently associated with psychedelic use, notably those related to postexperience dissociation (Schifano et al., 2019). The inclusion of structured preparation and integration phases, even within a nondirective model, reduces the likelihood of adverse effects (Feduccia et al., 2023). The continuous presence of trained professionals, albeit in a low-directiveness stance, promoted a greater sense of safety, while the focus on postsession integration provided essential support for assimilating emerging content, as reported by some participants. In this way, the protocol balances comfort and safety, allowing intense experiences to be lived safely, with minimized risk of adverse effects, especially among participants who were prescreened, prepared, and deemed fit for the process.

Despite its contributions, this study presents limitations. First, it involved a nonclinical sample composed of healthy volunteers with prior psychedelic experience, which limits the generalizability of the findings to clinical populations, such as individuals with depression. This sampling choice, however, was deliberate and ethically grounded, as the study corresponds to a Phase I clinical trial. At this initial stage of investigation, the recruitment of healthy volunteers with prior experience with the substance was adopted as a risk-minimization strategy, in accordance with ethical principles and international guidelines (Johnson et al., 2008) for psychedelic research, reducing the likelihood of unexpected adverse reactions in individuals who were completely naïve to the experience. Furthermore, although the mandala and questionnaire tools proved valuable, the absence of a control group limits the ability to isolate their specific effects. Additional limitations include the overlap of roles between researcher and therapist, which may introduce bias in session facilitation and data interpretation; participants' prior exposure to psychedelics, which could influence expectations and subjective reports; and the lack of a comparative arm, making it difficult to directly assess the relative effectiveness of the proposed protocol.

Conclusion

This study presents a novel, resource-efficient, and participant-centered protocol for administering inhaled DMT in a clinical setting. By prioritizing noninvasiveness, physical and emotional comfort, and structured integration, the protocol provides a

feasible model for future psychedelic interventions, particularly within public health systems. Key elements, such as using the inhalation route, preparatory sessions, touch-based support, and symbolic tools like mandalas, contributed to a sense of safety, autonomy, and meaning-making throughout the experience. As interest in the therapeutic use of psychedelics grows, the development of accessible, ethically grounded, and integrative models like this one will be essential for translating scientific promise into real-world mental health care.

References

Alsbrooks, K., & Hoerauf, K. (2022). Prevalence, causes, impacts, and management of needle phobia: An international survey of a general adult population. *PLOS ONE*, *17*(11), Article e0276814. https://doi.org/10.1371/journal.pone.0276814

Averill, L. A., & Abdallah, C. G. (2022). Investigational drugs for assisting psychotherapy for posttraumatic stress disorder (PTSD): Emerging approaches and shifting paradigms in the era of psychedelic medicine. *Expert Opinion on Investigational Drugs*, *31*(2), 133–137. https://doi.org/10.1080/13543784.2022.2035358

Back, A., Myers, S., Guy, J., Perez, J., Lazar Thorn, L., & McGregor, B. (2024). Evolving guidelines for the use of touch during a clinical trial of group psilocybin-assisted therapy. *Psychedelic Medicine*, *2*(4), 187–191. https://doi.org/10.1089/psymed.2023.0069

Barker, S. A. (2018). N, N-Dimethyltryptamine (DMT), an endogenous hallucinogen: Past, present, and future research to determine its role and function. *Frontiers in Neuroscience*, *12*, Article 536. https://doi.org/10.3389/fnins.2018.00536

Barker, S. A. (2022). Administration of N,N-dimethyltryptamine (DMT) in psychedelic therapeutics and research and the study of endogenous DMT. *Psychopharmacology*, *239*(6), 1749–1763. https://doi.org/10.1007/s00213-022-06065-0

Barrett, F. S., & Griffiths, R. R. (2018). Classic hallucinogens and mystical experiences: Phenomenology and neural correlates. In A. L. Halberstadt, F. X. Vollenweider, & D. E. Nichols (Eds.), *Behavioral neurobiology of psychedelic drugs* (pp. 393–430). Springer. https://doi.org/10.1007/7854_2017_474

Barros, H., Falchi-Carvalho, M., Maia, L. O., Laborde, S., Palhano-Fontes, F., Wießner, I., Arruda-Sanchez, T., & Araujo, D. B. (2025). Expressive resource in a clinical psychedelic study: Art as an integration tool. *Progress in Brain Research*, *296*, 131–146. https://doi.org/10.1016/bs.pbr.2025.07.004

Bathje, G. J., Majeski, E., & Kudowor, M. (2022). Psychedelic integration: An analysis of the concept and its practice. *Frontiers in Psychology*, *13*, Article 824077. https://doi.org/10.3389/fpsyg.2022.824077

Bender, D. A., Nayak, S. M., Siegel, J. S., Hellerstein, D. J., Ercal, B. C., & Lenze, E. J. (2025). Psychological support approaches in psychedelic therapy: Results from a survey of psychedelic practitioners. *The Journal of Clinical Psychiatry*, *86*(1), Article 24m15521. https://doi.org/10.4088/JCP.24m15521

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Brennan, W., Kelman, A. R., & Belser, A. B. (2023). A systematic review of reporting practices in psychedelic clinical trials: Psychological support, therapy, and psychosocial interventions. *Psychedelic Medicine*, *1*(4), 218–229. https://doi.org/10.1089/psymed.2023.0007

Carbonaro, T. M., & Gatch, M. B. (2016). Neuropharmacology of *N*,*N*-dimethyltryptamine. *Brain Research Bulletin*, *126*(Pt. 1), 74–88. https://doi.org/10.1016/j.brainresbull.2016.04.016

Cavarra, M., Falzone, A., Ramaekers, J. G., Kuypers, K. P. C., & Mento, C. (2022). Psychedelic-assisted psychotherapy-A systematic review of associated psychological interventions. *Frontiers in Psychology*, *13*, Article 887255. https://doi.org/10.3389/fpsyg.2022.887255

Chaves, C., Dos Santos, R. G., Dursun, S. M., Tusconi, M., Carta, M. G., Brietzke, E., & Hallak, J. E. C. (2024). Why N,N-dimethyltryptamine matters: Unique features and therapeutic potential beyond classical psychedelics. *Frontiers in Psychiatry*, *15*, Article 1485337. https://doi.org/10.3389/fpsyt.2024.1485337

Cott, C., & Rock, A. (2008). Phenomenology of N,N-dimethyltryptamine use: A thematic analysis. *Journal of Scientific Exploration*, *22*(3), 298–316.

D'Souza, D. C., Syed, S. A., Flynn, L. T., Safi-Aghdam, H., Cozzi, N. V., & Ranganathan, M. (2022). Exploratory study of the dose-related safety, tolerability, and efficacy of dimethyltryptamine (DMT) in healthy volunteers and major depressive disorder. *Neuropsychopharmacology*, *47*(10), 1854–1862. https://doi.org/10.1038/s41386-022-01344-y

Da Silveira, N. (1981). *Imagens do inconsciente*. Alhambra.

Da Silveira, N. (1992). *O mundo das imagens*. Editora Ática.

Davis, A. K., Barrett, F. S., & Griffiths, R. R. (2020). Psychological flexibility mediates the relations between acute psychedelic effects and subjective decreases in depression and anxiety. *Journal of Contextual Behavioral Science*, *15*, 39–45. https://doi.org/10.1016/j.jcbs.2019.11.004

Devenot, N., Seale-Feldman, A., Smith, E., Noorani, T., Garcia-Romeu, A., & Johnson, M. W. (2022). Psychedelic identity shift: A critical approach to set and setting. *Kennedy Institute of Ethics Journal*, *32*(4), 359–399. https://doi.org/10.1353/ken.2022.0022

Earleywine, M., Low, F., Lau, C., & De Leo, J. (2022). Integration in psychedelic-assisted treatments: Recurring themes in current providers' definitions, challenges, and concerns. *Journal of Humanistic Psychology*. Advance online publication. https://doi.org/10.1177/00221678221085800

Eisner, B. (1997). Set, setting, and matrix. *Journal of Psychoactive Drugs*, *29*(2), 213–216. https://doi.org/10.1080/02791072.1997.10400190

Falchi-Carvalho, M., Barros, H., Bolcont, R., Laborde, S., Wießner, I., Ruschi B Silva, S., Montanini, D., Barbosa, D. C., Teixeira, E., Florence-Vilela, R., Almeida, R., de Macedo, R. K. A., Arichelle, F., Pantrigo, É. J., Costa-Macedo, J. V., Arcoverde, E., Galvão-Coelho, N., Araujo, D. B., & Palhano-Fontes, F. (2025). The antidepressant effects of vaporized N,N-dimethyltryptamine: An open-label pilot trial in treatment-resistant depression. *Psychedelic Medicine*, *3*(1), 48–52. https://doi.org/10.1089/psymed.2024.0002

Falchi-Carvalho, M., Palhano-Fontes, F., Wießner, I., Barros, H., Bolcont, R., Laborde, S., Ruschi B. Silva, S., Montanini, D., C. Barbosa, D., Teixeira, E., Florence-Vilela, R., Almeida, R., K. A. de Macedo, R., Arichelle, F., Pantrigo, J. É., V. Costa-Macedo, J., da Cruz Nunes, J. A., de Araújo Costa Neto, L. A., Nunes Ferreira, L. F., … B. Araujo, D. (2025). Rapid and sustained antidepressant effects of vaporized N,N-dimethyltryptamine: A phase 2a clinical trial in treatment-resistant depression. *Neuropsychopharmacology*, *50*(6), 895–903. https://doi.org/10.1038/s41386-025-02091-6

Falchi-Carvalho, M., Wießner, I., Silva, S. R. B., O Maia, L., Barros, H., Laborde, S., Arichelle, F., Tullman, S., Silva-Costa, N., Assunção, A., Almeida, R., Pantrigo, É. J., Bolcont, R., Costa-Macedo, J. V., Arcoverde, E., Galvão-Coelho, N., Araujo, D. B., & Palhano-Fontes, F. (2024). Safety and tolerability of inhaled *N*,*N*-dimethyltryptamine (BMND01 candidate): A phase I clinical trial. *European Neuropsychopharmacology*, *80*, 27–35. https://doi.org/10.1016/j.euroneuro.2023.12.006

Feduccia, A., Agin-Liebes, G., Price, C. M., Grinsell, N., Paradise, S., & Rabin, D. M. (2023). The need for establishing best practices and gold standards in psychedelic medicine. *Journal of Affective Disorders*, *332*, 47–54. https://doi.org/10.1016/j.jad.2023.03.083

Florineth, G. A., Klima, I., Boeker, A. L., Catzeflis, P., Wopfner, A., Denier, N., Bracht, T., Adorjan, K., Pfammatter, M., Müller, F., & Soravia, L. M. (2026). Psychological therapy quantity and depressive symptom reduction in psychedelic-assisted therapy: A systematic review and meta-analysis. *JAMA Network Open*, *9*(1), Article e2554843. https://doi.org/10.1001/jamanetworkopen.2025.54843

Frymann, T., Whitney, S., Yaden, D. B., & Lipson, J. (2022). The psychedelic integration scales: Tools for measuring psychedelic integration behaviors and experiences. *Frontiers in Psychology*, *13*, Article 863247. https://doi.org/10.3389/fpsyg.2022.863247

Gallimore, A. R., & Strassman, R. J. (2016). A model for the application of target-controlled intravenous infusion for a prolonged immersive DMT psychedelic experience. *Frontiers in Pharmacology*, *7*, Article 211. https://doi.org/10.3389/fphar.2016.00211

Golden, T. L., Magsamen, S., Sandu, C. C., Lin, S., Roebuck, G. M., Shi, K. M., & Barrett, F. S. (2022). Effects of setting on psychedelic experiences, therapies, and outcomes: A rapid scoping review of the literature. *Current Topics in Behavioral Neurosciences*, *56*, 35–70. https://doi.org/10.1007/7854_2021_298

Goodwin, G. M., Aaronson, S. T., Alvarez, O., Arden, P. C., Baker, A., Bennett, J. C., Bird, C., Blom, R. E., Brennan, C., Brusch, D., Burke, L., Campbell-Coker, K., Carhart-Harris, R., Cattell, J., Daniel, A., DeBattista, C., Dunlop, B. W., Eisen, K., Feifel, D., … Malievskaia, E. (2022). Single-dose psilocybin for a treatment-resistant episode of major depression. *The New England Journal of Medicine*, *387*(18), 1637–1648. https://doi.org/10.1056/nejmoa2206443

Grof, S., Doblin, R., Grof, B., & Tarnas, R. (2019). *The way of the psychonaut: Encyclopedia for inner journeys* (Vol. 2). Multidisciplinary Association for Psychedelic Studies.

Ham, R., Gardner, J., Carter, A., & Liknaitzky, P. (2025). *Participant experiences of therapeutic touch in psilocybin-assisted therapy* [Preprint]. OSF Preprints. https://doi.org/10.31219/osf.io/ypqa2_v2

Hartogsohn, I. (2017). Constructing drug effects: A history of set and setting. *Drug Science, Policy and Law*, *3*, Article 2050324516683325. https://doi.org/10.1177/2050324516683325

Hartogsohn, I. (2022). Modalities of the psychedelic experience: Microclimates of set and setting in hallucinogen research and culture. *Transcultural Psychiatry*, *59*(5), 579–591. https://doi.org/10.1177/13634615221100385

Johnson, M., Richards, W., & Griffiths, R. (2008). Human hallucinogen research: Guidelines for safety. *Journal of Psychopharmacology*, *22*(6), 603–620. https://doi.org/10.1177/0269881108093587

Jung, C. G. (1964). *Man and his symbols*. Aldus Books.

Jung, C. G. (1972). *Mandala symbolism* (Vol. 9i, Collected Works). Princeton University Press. https://doi.org/10.1515/9781400886043

Kaplan, J., Mandel, L. R., Stillman, R., Walker, R. W., VandenHeuvel, W. J. A., Gillin, J. C., & Wyatt, R. J.

(1974). Blood and urine levels of N,N-dimethyltryptamine following administration of psychoactive dosages to human subjects. *Psychopharmacologia*, *38*(3), 239–245. https://doi.org/10.1007/BF00421376

Labate, B. C., De Rose, I. S., & dos Santos, R. G. (2008). *Ayahuasca religions: A comprehensive bibliography and critical essays*. Multidisciplinary Association for Psychedelic Studies.

Lauri, M. A. (2011). Triangulation of data analysis techniques. *Papers on Social Representations*, *20*(2), 34.1–34.15. https://psr.iscte-iul.pt/index.php/PSR/article/view/449

Lawrence, D. W., Carhart-Harris, R., Griffiths, R., & Timmermann, C. (2022). Phenomenology and content of the inhaled N, N-dimethyltryptamine (N, N-DMT) experience. *Scientific Reports*, *12*(1), Article 8562. https://doi.org/10.1038/s41598-022-11999-8

Leary, T., Metzner, R., & Alpert, R. (1964). *The psychedelic experience: A manual based on the Tibetan Book of the Dead*. University Books.

Luoma, J. B., Allen, L. R., Gold, V., & Stauffer, C. (2024). Getting in touch with touch: The importance of studying touch in MDMA-assisted therapy and the development of a new self-report measure. *Psychedelic Medicine*, *2*(1), 25–32. https://doi.org/10.1089/psymed.2023.0033

Luoma, J. B., & LeJeune, J. (2025). From theory to practice: The importance of operationalizing and measuring ethical touch in psychedelic-assisted therapy. *The American Journal of Bioethics*, *25*(1), 120–123. https://doi.org/10.1080/15265161.2024.2433425

Maguire, M., & Delahunt, B. (2017). Doing a thematic analysis: A practical, step-by-step guide for learning and teaching scholars. *All Ireland Journal of Higher Education*, *9*(3), 3351–3359. https://doi.org/10.62707/aishej.v9i3.335

Maia, L. O., Daldegan-Bueno, D., Wießner, I., Araujo, D. B., & Tófoli, L. F. (2023). Ayahuasca's therapeutic potential: What we know—And what not. *European Neuropsychopharmacology*, *66*, 45–61. https://doi.org/10.1016/j.euroneuro.2022.10.008

Marseille, E., Bertozzi, S., & Kahn, J. G. (2022). The economics of psychedelic-assisted therapies: A research agenda. *Frontiers in Psychiatry*, *13*, Article 1025726. https://doi.org/10.3389/fpsyt.2022.1025726

Maturana, H. R., & Varela, F. J. (1987). *The tree of knowledge: The biological roots of human understanding*. New Science Library/Shambhala Publications.

McNamee, S., Devenot, N., & Buisson, M. (2023). Studying harms is key to improving psychedelic-assisted therapy–Participants call for changes to research landscape. *JAMA Psychiatry*, *80*(5), 411–412. https://doi.org/10.1001/jamapsychiatry.2023.0099

Millière, R. (2017). Looking for the self: Phenomenology, neurophysiology and philosophical significance of drug-induced ego dissolution. *Frontiers in Human Neuroscience*, *11*, Article 245. https://doi.org/10.3389/fnhum.2017.00245

Mitchell, J. M., Bogenschutz, M., Lilienstein, A., Harrison, C., Kleiman, S., Parker-Guilbert, K., Ot'alora, G. M., Garas, W., Paleos, C., Gorman, I., Nicholas, C., Mithoefer, M., Carlin, S., Poulter, B., Mithoefer, A., Quevedo, S., Wells, G., Klaire, S. S., van der Kolk, B., … Doblin, R. (2021). MDMA-assisted therapy for severe PTSD: A randomized, double-blind, placebo-controlled phase 3 study. *Nature Medicine*, *27*(6), 1025–1033. https://doi.org/10.1038/s41591-021-01336-3

Mithoefer, M. C. (2015). *A manual for MDMA-assisted psychotherapy in the treatment of posttraumatic stress disorder*. Multidisciplinary Association for Psychedelic Studies.

Mithoefer, M. C., Wagner, M. T., Mithoefer, A. T., Jerome, L., & Doblin, R. (2011). The safety and efficacy of ±3,4-methylenedioxymethamphetamine-assisted psychotherapy in subjects with chronic, treatment-resistant posttraumatic stress disorder: The first randomized controlled pilot study. *Journal of Psychopharmacology*, *25*(4), 439–452. https://doi.org/10.1177/0269881110378371

Naeem, M., Ozuem, W., Howell, K., & Ranfagni, S. (2023). A step-by-step process of thematic analysis to develop a conceptual model in qualitative research. *International Journal of Qualitative Methods*, *22*, Article 16094069231205789. https://doi.org/10.1177/16094069231205789

Neitzke-Spruill, L., Beit, C., Averill, L. A., & McGuire, A. L. (2025). Supportive touch in psychedelic assisted therapy. *The American Journal of Bioethics*, *25*(1), 29–39. https://doi.org/10.1080/15265161.2024.2433428

Nowell, L. S., Norris, J. M., White, D. E., & Moules, N. J. (2017). Thematic analysis: Striving to meet the trustworthiness criteria. *International Journal of Qualitative Methods*, *16*(1), Article 1609406917733847. https://doi.org/10.1177/1609406917733847

Pahnke, W. N. (1963). *Drugs and mysticism: An analysis of the relationship between psychedelic drugs and the mystical consciousness*. [Doctoral dissertation]. Harvard University.

Palhano-Fontes, F., Barreto, D., Onias, H., Andrade, K. C., Novaes, M. M., Pessoa, J. A., Mota-Rolim, S. A., Osório, F. L., Sanches, R., dos Santos, R. G., Tófoli, L. F., de Oliveira Silveira, G., Yonamine, M., Riba, J., Santos, F. R., Silva-Junior, A. A., Alchieri, J. C., Galvão-Coelho, N. L., Lobão-Soares, B., … Araújo, D. B. (2019). Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant depression: A randomized placebo-controlled trial. *Psychological Medicine*,

49(4), 655–663. https://doi.org/10.1017/S0033291718001356

Palhano-Fontes, F., Soares, B. L., Galvão-Coelho, N. L., Arcoverde, E., & Araujo, D. B. (2021). Ayahuasca for the treatment of depression. In F. S. Barrett & K. H. Preller (Eds.), *Current topics in behavioral neurosciences* (Vol. 56, pp. 113–124). Springer. https://doi.org/10.1007/7854_2021_277

Petitmengin, C. (2006). Describing one's subjective experience in the second person: An interview method for the science of consciousness. *Phenomenology and the Cognitive Sciences*, *5*(3–4), 229–269. https://doi.org/10.1007/s11097-006-9022-2

Phelps, J. (2017). Developing guidelines and competencies for the training of psychedelic therapists. *Journal of Humanistic Psychology*, *57*(5), 450–487. https://doi.org/10.1177/0022167817711304

Pilecki, B., Luoma, J. B., Bathje, G. J., Rhea, J., & Narloch, V. F. (2021). Ethical and legal issues in psychedelic harm reduction and integration therapy. *Harm Reduction Journal*, *18*(1), Article 40. https://doi.org/10.1186/s12954-021-00489-1

Pontual, A. A. D. D., Tófoli, L. F., Corradi-Webster, C. M., van Oorsouw, K., Delgado, A. R. O., & Ramaekers, J. G. (2022). The influence of ceremonial settings on mystical and challenging experiences occasioned by ayahuasca: A survey among ritualistic and religious ayahuasca users. *Frontiers in Psychology*, *13*, Article 857372. https://doi.org/10.3389/fpsyg.2022.857372

Pronovost-Morgan, C., Greenway, K. T., & Roseman, L. (2025). An international Delphi consensus for reporting of setting in psychedelic clinical trials. *Nature Medicine*, *31*(7), 2186–2195. https://doi.org/10.1038/s41591-025-03685-9

Ramaekers, J. G., Reckweg, J. T., & Mason, N. L. (2025). Benefits and challenges of ultra-fast, short-acting psychedelics in the treatment of depression. *The American Journal of Psychiatry*, *182*(1), 33–46. https://doi.org/10.1176/appi.ajp.20230890

Robinson, O. C., Evans, J., Luke, D., McAlpine, R., Sahely, A., Fisher, A., Sundeman, S., Ketzitzidou Argyri, E., Murphy-Beiner, A., Michelle, K., & Prideaux, E. (2024). Coming back together: A qualitative survey study of coping and support strategies used by people to cope with extended difficulties after the use of psychedelic drugs. *Frontiers in Psychology*, *15*, Article 1369715. https://doi.org/10.3389/fpsyg.2024.1369715

Ruffell, S. G. D., Crosland-Wood, M., Palmer, R., Netzband, N., Tsang, W., Weiss, B., Gandy, S., Cowley-Court, T., Halman, A., McHerron, D., Jong, A., Kennedy, T., White, E., Perkins, D., Terhune, D. B., & Sarris, J. (2023). Ayahuasca: A review of historical, pharmacological, and therapeutic aspects. *PCN Reports: Psychiatry and Clinical Neurosciences*, *2*(4), Article e146. https://doi.org/10.1002/pcn5.146

Sanches, R. F., de Lima Osório, F., Dos Santos, R. G., Macedo, L. R. H., Maia-de-Oliveira, J. P., Wichert-Ana, L., de Araujo, D. B., Riba, J., Crippa, J. A. S., & Hallak, J. E. C. (2016). Antidepressant effects of a single dose of ayahuasca in patients with recurrent depression: A SPECT study. *Journal of Clinical Psychopharmacology*, *36*(1), 77–81. https://doi.org/10.1097/JCP.0000000000000436

Sanders, J. W., Millière, R., Daily, Z. G., Carhart-Harris, R., & Timmermann, C. (2024). *DMT micro-phenomenology* [Preprint]. OSF. https://osf.io/2m9d4

Schifano, F., Napoletano, F., Chiappini, S., Orsolini, L., Guirguis, A., Corkery, J. M., Bonaccorso, S., Ricciardi, A., Scherbaum, N., & Vento, A. (2019). New psychoactive substances (NPS), psychedelic experiences and dissociation: Clinical and clinical pharmacological issues. *Current Addiction Reports*, *6*(2), 140–152. https://doi.org/10.1007/s40429-019-00249-z

Shanon, B. (2003). *The antipodes of the mind: Charting the phenomenology of the ayahuasca experience*. Oxford University Press. https://doi.org/10.1093/oso/9780199252923.001.0001

Stanicic, F., Zah, V., Grbic, D., & De Angelo, D. (2024). Cost-effectiveness of midomafetamine-assisted therapy (MDMA-AT) in chronic and treatment-resistant post-traumatic stress disorder of moderate or higher severity: A health-economic model. *PLOS ONE*, *19*(11), Article e0313569. https://doi.org/10.1371/journal.pone.0313569

Strassman, R. J. (2001). *DMT: The spirit molecule*. Park Street Press.

Terry, G., Hayfield, N., Clarke, V., & Braun, V. (2017). Thematic analysis. In G. Smith, E. Lyons, & S. Larkin (Eds.), *The SAGE handbook of qualitative research in psychology* (2nd ed., pp. 17–36). SAGE Publications. https://doi.org/10.4135/9781526405555.n2

Timmermann, C., Roseman, L., Schartner, M., Milliere, R., Williams, L. T. J., Erritzoe, D., Muthukumaraswamy, S., Ashton, M., Bendrioua, A., Kaur, O., Turton, S., Nour, M. M., Day, C. M., Leech, R., Nutt, D. J., & Carhart-Harris, R. L. (2019). Neural correlates of the DMT experience assessed with multivariate EEG. *Scientific Reports*, *9*(1), Article 16324. https://doi.org/10.1038/s41598-019-51974-4

Van Elk, M., & Fried, E. I. (2023). History repeating: Guidelines to address common problems in psychedelic science. *Therapeutic Advances in Psychopharmacology*, *13*, Article 20451253231198466. https://doi.org/10.1177/20451253231198466

Villiger, D. (2025). Patient–therapist relationship in psychedelic-assisted therapy: Implications for future real-world settings. *General Hospital Psychiatry*, *96*, 54–59. https://doi.org/10.1016/j.genhosppsych.2025.06.003

Vogt, S. B., Ley, L., Erne, L., Straumann, I., Becker, A. M., Klaiber, A., Holze, F., Vandersmissen, A.,

Mueller, L., Duthaler, U., Rudin, D., Luethi, D., Varghese, N., Eckert, A., & Liechti, M. E. (2023). Acute effects of intravenous DMT in a randomized placebo-controlled study in healthy participants. *Translational Psychiatry*, *13*(1), Article 172. https://doi.org/10.1038/s41398-023-02477-4

Yaden, D. B., & Griffiths, R. R. (2021). The subjective effects of psychedelics are necessary for their enduring therapeutic effects. *ACS Pharmacology & Translational Science*, *4*(2), 568–572. https://doi.org/10.1021/acsptsci.0c00194

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