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Expectation vs. Fantasy: Exploring Epistemic Value in the Biomedicalization of Psychedelic Assisted Therapy (PAT)

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Abstract

Purpose: The purpose of this dissertation is to explore how respective epistemic value systems contribute to the process of PAT via the different expectations held by clinicians and clients.

Design and Method: A qualitative research method was deployed, conducting seven one-to-one semi-structured interviews with clinical trial researchers, practising psychotherapists, or postgraduate students involved in psychedelic-assisted therapy. A reflexive thematic analysis was used to report how the participants understood the epistemic influence on expectations impacting outcomes of PAT.

Results: The results are presented through descriptions and examples formulated through epistemological concepts expressed in the semi-structured interviews. The themes are Converging Knowledge Dynamics, the Influence of Set and Setting, and the Assessments of Future Orientations.

Conclusion: The reflective thematic method of analysis addressed the key components of the PAT process impacted by expectations; and vice versa. Collaborations of Global North and Global South epistemological frameworks—including epistemic authority, rationalism,

existentialism, and empiricism— are discussed. Finally, reflexive questions for further qualitative research methods are prompted in addition to this dissertation's findings.

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Chapter 1: Introduction

What was once known as a 'free-love' movement has been recategorised and upholstered to the announcement of a renaissance era of psychedelics (Dupuis and Veissière, 2022). Within this re-emergence comes questions of how its mechanisms will be different, in terms of regulation across domains of spiritual, recreational, and medicinal use. Psychedelic-assisted therapy (PAT) is the utilisation of psychedelic plants and derivatives that aims to subject an altered-state of consciousness (ASC)(Barbosa et al., 2005). This therapeutic approach is intended to facilitate deeper introspection and understanding of one's psyche. Ultimately aiming to enhance one's quality of life (Labate and Antunes, 2024). This course of therapy within clinical research and practice consists of multiple pre and post therapeutic sessions that help guide and monitor the mental health of the participants and patients' interaction with the psychedelic. Oxford's 3rd Edition Dictionary term 'psyche' originates from the Greek word for 'soul' while the term 'delia' then comes from the "visible, manifestant" (McKean, 2003). To conceptualise this practice, one must provoke an inward confrontation with one's inner self.

Psychedelics, which serve as the catalyst for this introspection, are currently understood to be either pharmacologically synthesised compounds or naturally occurring plants derivatives that induce an ASC (Barbosa et al., 2005; Talin and Sanabria, 2017; Noorani, 2019).

Psychedelics are most commonly obtained from fungi and tree derivatives, and they comprise a list of hallucinogens, dissociatives and are sometimes referred to as entheogens. These include LSD (Lysergic acid diethylamide), DMT (N-Dimethyltryptamine) psilocybin (magic mushrooms), MDMA (Methylenedioxy methamphetamine), ketamine, and mescaline (Van Elk and Fried, 2023). The two main psychedelics being applied and discussed in current research, including in this dissertation, are MDMA and psilocybin. MDMA is used to treat patients with PTSD, while psilocybin most commonly alleviates symptoms of anxiety and depressive disorders, especially in treatment-resistant patients (Carhart-Harris et. al, 2016a&b). Healthy participants also report life-changing meaningful experiences that aid in a deeper understanding of themselves and surrounding properties of the world (Van Elk and Fried, 2023). To successfully achieve this understanding, the appropriate atmosphere and mindset throughout the experience is vital.

This alternative mode of delivering mental health relief introduces a myriad of factors that contribute to its success. Contributing to its hopeful success would be how it differs in delivery, process, and outcomes from current categories of antidepressant, antianxiety, and antipsychotic medications and other forms of therapy. Mobilising the modalities of psychedelics - involving the different "physical, social, and cultural environments" - requires multiple disciplines of expertise (Hartogsohn, 2022, pg. 579). One discipline contributing to the mobilisation has been in policy concerning the fluctuating legal statuses of the psychoactive substances and medicines around the world. Currently in North America, psychedelics are moving from schedule one drugs to decriminalised at different paces among federal and state law. This varies among populations including Indigenous populations and clinical therapeutic practices in some states such as Oregon and Colorado (De et al., 2023). Comparatively, the psychedelic community in the United Kingdom has fought to have access to use psychedelics in research. However, psychedelics currently not only "share the word 'drug' with compounds that we know are very addictive like heroin, cocaine etc" (Fielding, 2023) but are also held within the same Class A as such drugs (UK Government). Outside of these two main leaders in research, different regions of the world have allowed access for different reasons (Inserra, 2019). For example, some South American countries allow access for expression of religious freedom while European affiliated countries (such as The Netherlands and Germany) allow access for regulated recreational or medicinal prescribed psilocybin (Chesak, 2024)

The psychedelic renaissance comes with challenges that are currently under investigation, including obtaining full consent, identifying the optimal set and setting for psychedelics in medicine, wide and diverse accessibility, blinding efficacy, adverse effects (such as worsening mental health), and identifying regulatory brain functions when entering into an ineffable ASC (Carhart-Harris et al., 2018; Hutten et al., 2024). The collection of these factors emphasise the need for responsible and equitable access. Unlike the mainstream process of approving a prescription, psychedelic research often requires preparatory sessions and compulsory therapy alongside the consumption of the substance.

While the space for addressing current research expands, the contentious nature of this topic intensifies the discussions within this dissertation and those within the sources that informed the RQ. This includes the current deliberations after the FDA denied approval for

MDMA to be legally used to treat PTSD. It is important to mention there is no evidence that this category of medication has addictive properties. The proposal for approval was denied because it did not represent a strong argument "that the risks of MDMA, also known as ecstasy, outweigh its benefits" (Reardon, 2024).

A primary concern to many within the field is ensuring full-dosing practices with this medicine is intentionally implemented using a combined prescription of therapy (Carhart-Harris and Goodwin, 2017). This concern, among others, is part of a broader conversation that involves a complex evaluation of the sources and frameworks through which these proposals are presented. One consistency promoted throughout the voices within psychedelic research is the use of reflexivity of all agents involved; reflecting on the origin of information, diverse identities represented, and innate biases and expectations. Other than the participant and their client, the psychedelic is also given agentive properties for the culture it represents, history of use, and identity it holds.

1. 1 Aims & Objectives

The aim of this study is to elucidate how my participants and their clients' expectations of the therapeutic experience, constructed through knowledge systems, may impact individual treatment, thus the overall trajectory of PAT biomedicalisation. While achieving these aims, three objectives will be addressed. The first objective evaluates how the origins of epistemological perspectives influence the discourse of PAT. Epistemology is the theory of knowledge which determines what is accepted as verified knowledge thus examines the three courses of rationalism, empiricism, and existentialism for how we obtain or produce that knowledge. The second objective is to understand the epistemological characteristics inherent in the therapeutic practice by constructing semi-structured interviews with clinical trial researchers and therapists. Lastly, examining the impact of cultural perspectives on the efficacious components of set and setting within PAT clinical trials contexts.

1.2 Research Question

The dissertation will seek to answer the following research question (RQ): How do epistemic value systems within the biomedicalisation of psychedelic-assisted therapy (PAT) shape the expectations of mental health treatment among clinical trial researchers and

psychotherapists? Furthermore, I wish to address the following sub questions: What are the phenomenological expectations or assumptions influencing the outcomes of PAT from the perspectives of researchers and therapists? How can cultural competence be integrated into the biomedicalisation of PAT to enhance its efficacy and effectiveness?

1.3 Argument

By answering these research questions, this dissertation will argue that expectations formed from various epistemic structures influence the therapeutic process of PAT. By epistemics, I refer to systems of knowledge in both academic expert settings and sociological lay settings (Arksey, 1994). These settings combine education of pharmacology and psychology with popular media, individual identity and Indigenous historical practices of PAT (Hartogsohn, 2022). Researchers are being interviewed to gain access to vital aspects of these systemic mechanisms of psychedelic knowledge dissemination and epistemic authority. Among those aspects is the researcher's dedication to improve the cultural integrity of this therapeutic panacea.

Applications of Hartogsohn's (2022) various modalities of set and setting, will construct an idea of successful therapeutic experiences in PAT (Tupper and Labate, 2015). Among the modalities of set and setting is the influence of expectations. This dissertation aims to highlight this influence while suggesting ways to improve the 'pharmacological revolution' that is PAT (Dupuis and Veissière, 2022). The suggestions will support the idea that psychedelics should be taken as a cohesive therapeutic prescription to address mental health issues rather than be mainstreamed for monetisation and possible misuse (Meneu, 2018; Labate and Antunes, 2024). This therapeutic process is necessary to provide support in all stages of the ingestion of psychedelics and most importantly to manage expectations through sessions with psychotherapeutic professionals.

The argument comes with influence from those who advocate as voices for Indigenous communities that have been using plants with psychedelic properties for centuries as part of their spiritual and cultural rituals (Labate and Antunes, 2024). The integration of their competence is explored in ways such as the origin of the psychedelics being used. The pharmacological properties of the psychedelic used in clinical trials have been manufactured in the Global North for purposes of establishing consistency in dosing (Ona et al., 2019). The term 'Western' refers to the allopathic, bio-medicalised, pharmaceutically driven, conventional medicine while 'Global

North' will refer to geographical regions using such medicine. Honouring cultural significance within this context does not just mean respecting its geographical origins and Indigenous epistemological foundations of the practice. It also includes respecting each individual that enters the practice and how their identities will influence the practice.

1.5 Purpose

At this time, both you and I have made our own predictions and formulated our own expectations for the results of this dissertation. I approach this dissertation with the premise that human behaviour, often unconsciously, tends to create expectations (Kirsch, 1999). Psychedelics can deconstruct limits or dysregulate brain functions (Carhart-Harris, 2024), which could include disrupting patterns of preparation, such as building expectations. My goal is to explore where these expectations of psychedelics originate from and their scope of influence in application of this renaissance of mental health therapy. Furthermore, I aim to understand how the knowledge dynamics of the expectations impact the therapeutic process. Finally, I enter this research with influence from Voltaire and literary alterations from Stan Lee; "with great expectations, comes great responsibility" (Lee and Ditko, 1962).

From the words of a philosopher and founder of psychological movement of functionalism, William James in the 1900's stated "it is a complex idea, philosophically subtle and epistemological multi-dimensional" which sums the past, present, and contributes to trajectory of psychedelic understanding (Cole-Turner, 2021, pg. 5). The mystique and ineffable quality of these substances have prompted a deeper expansion upon its epistemological, religious/spiritual, cultural, political, philosophical, and psychological modalities of ASC in therapeutic advantages (Hartosgen, 2022).

1.6 Outline

The following chapter will review the available literature on history of perceptions of psychedelic response, epistemic injustices, expectations and the overall goals of PAT. The next chapter will consider the nature of the qualitative methodology used in this research including demographics of the sample population, how they were recruited, ethical practices and how the data they provided was sorted and analysed. The Results chapter will report Converging Knowledge Dynamics, the Influence of Set and Setting, and the Assessments of Future

Orientations. The Discussion chapter will provide an analysis with explanations of how the participants' responses impact the discourse of PAT. Lastly, the Conclusion will review the epistemological frameworks discussed in this dissertation to clarify how sources of knowledge, belief systems, and educational priorities shape expectations in the process of PAT.

Chapter 2: Literature Review

This chapter will review existing literature about using psychedelics in mental health therapy as a catalyst to explore different states of consciousness. Particular focus of the report will be on the history of perceptions of psychedelic engagements, epistemic injustices, expectations and the overall goals of PAT.

2.1 Summary

Exploring different states of consciousness requires analysis from different disciplines. One discipline dissects the biological and chemical reactions occurring within the brain that show evidence of "a tumult of new neuronal pathways" in comparison to the absence of psilocybin (Sheldrake, 2020). Briefly, the sources that discuss neurological occurrences throughout the duration of the therapy note the activity in the brain undergoes notable cerebral fluxes. The other discipline primarily discusses the cultural, anthropological, and sociological considerations in the biomedicalisation of PAT (Carhart-Harris and Goodwin, 2017; Hutten et.al, 2024; Labate et.al, 2022; Virtanen, 2014). The latter recognises nuances of validity within the discussion of psychedelic efficacy. While I separate the two here, there is a necessary combination to fully understand the trajectory of the integration into medical practice. Achieving this involves recognising historical foundations, expectations of the therapy, and epistemic justice. Specifically, to present evidence to those engaging in the therapy and ultimately to influence policy entities for prospective psychedelic application in mental health.

2.2 History of perceptions of psychedelic responses

Dating back to the early 1900's, William James established the word "mystical" to connect cross-cultural features of spirituality and experiences associated with psychedelic consumption. James' "mystical" has been widely used throughout the century (Hartogsohn 2022; Johnson et.al, 2019; Labate and Tupper 2015; Vargas-Pérez, 2013; Furst, 1976). However, a more "standard fixture in the most recent technical articles" expresses the preference to describe the experience from 'mystical' to having a "noetic quality" (Cole-Turner, 2022, pg. 1). When dissected, this description immediately exposes the epistemological relationship between any exposure to psychedelics by highlighting the intellectual revelations possible. Richard Evans Schultes used this to emulate his appreciation of Spanish roots, describing some plant-derived psychedelics as 'flesh of the gods'. He reported in his studies at Harvard about the ceremonial

segments that were used to heal sicknesses, gain guidance, and get deeper insights into the unknown (Cole-Turner, 2021). This occurred simultaneously in the 1930's with Albert Hofmann's significant isolation of LSD from ergot fungi through pharmacological properties and methods in Switzerland (Pilecki et al., 2021). The licit studies at Harvard expanded into the Psilocybin Project in the 1960's when Thomas Leary gained interest after hearing of his colleagues "visionary voyage" with a Shaman in Mexico named Maria Sabina (Sheldrake, 2022 pg.130). The generosity of Sabina to share her knowledge came at the cost of her home and life after the assurance of her anonymity was violated (Sheldrake, 2022).

The resurgence of the psychedelic renaissance, rooted in the historical context of U.S. President Nixon's 'war on drugs,' emerged from the underground efforts of advocates who navigated the criminalisation of psychedelics to sustain and advance research, knowledge, and practice in the field, despite significant societal and legal challenges (Hartogsohn, 2022). These challenges led to the degradation of a connection to a deeper sense of knowing and a deeper sense of self. Sustaining the integrity of psychedelics was not achieved through peace signs and spreading love. Rather, it was achieved through the arduous struggle to maintain these practices and disseminate knowledge 'underground'. The movement of the practice to 'underground' meant individuals within the psychedelic field were driven to a clandestine form of studying. Most research was informal while finding ways to understand factors such as safety, cost and benefits, and value of psychedelic components. Erik Davis was a large influence in identifying this as a "space of informality" for developing sub-cultures to contribute to the larger community of individuals seeking mental health help (Davis, 2024). During this time, an argument for patient expectations facilitating the efficacy of therapy began (Tinsley et al., 1988). The "space of informality" continues today with further subcultures of 'psychonauts' -individuals with experience exploring different states of consciousness with the regulation of psychedelics igniting passion for a mental health panacea.

Currently, psychedelics are also going through a process called 'biomedicalisation'. Biomedicalisation and its underlying theory is primarily influenced by the techno-scientific integration of medicine and secondarily, evolving social behaviours towards alternative medical practices (Clarke et.al., 2003). The concept of psychedelic biomedicalisation can be understood as the combination of the medicalisation and pharmaceuticalisation processes, or the transition of

psychedelics from an informal, spiritual practice to a medical and regulated practice (Milbauer, 2024). Biomedical research seeks application of psychedelics in various areas, including addiction, palliative care, obsessive-compulsive disorder, PTSD, and social anxiety (Noorani, 2019). Academic institutions such as Yale University, Imperial and King's College London continue to advance clinical trial research in these areas. They can now collaborate with forprofit organisations working to streamline access to psychedelics (Noorani, 2019). The collaboration with companies monetising the pharmaceuticalisation of psychedelics warrants scepticism of intentions and potential consequences concerning the mode and technique of administration. All of the contradicting and interlacing historical information is important to establish and understand the current climate of research and academic spaces in which this dissertation will enter.

However, the current and past renaissance of psychedelic research and the integration into Western medicine has yet to recognise the depreciating yet vital, challenging, and costly history of psychedelics within Indigenous communities (Cavnar and Labate, 2014). Robin Carhart-Harris and Guy Goodwin summarise the scientific field "as a putative aid to psychotherapy, but of course, it has an older cultural history as a constituent of magic mushrooms." (Carhart-Harris and Goodwin, 2017 pg. 2109). A significant ontological shift in Western research highlights cultural history beginning with the evidence of mushroom deities dated back to 2000 B.C. which are thought to suggest ritual consumption of psilocybin. Communities within the South American and North American borders have been using plants such as mescaline, peyote and strains of other 'magic mushrooms' to guide spiritual journeys that signify future existence among common people and simultaneously a deep connection to their past through ancestral communication (Sheldrake, 2022; Calabrese, 2013). This long history reinforces maintaining a mediating variable for the success of the treatment; this being consuming psychedelics strictly with the attendance of therapy with a Shaman or guide (Johnson et.al, 2008; Noorani, 2020; Hofmann, 1980; Virtanen, 2014).

2.3 Epistemic Injustice

Different waves of introducing psychedelics into Western power structures brought attempts at restraining the free use of natural medicinal and ritual practices in Indigenous communities (Gearin and Sáez, 2021; Feeney and Labate, 2022; Ona et al., 2021). This restraint

reinforces the assumptions that the Western approach held the epistemological power where "all nomenclature tends to make any item of knowledge more exoteric" causing what is understood as epistemic injustice (Ludwik Fleck, 1979, pg. 114). Epistemic injustice is defined as "someone who is wronged in their capacity as a giver of knowledge" (Fricker, 2008, pg.15). The concept of a psychedelic renaissance reinstates a colonialist framework by neglecting counternarratives and the contributions from marginalised groups both in the Global North and the Global South. Incorporating shamanic techniques and long-lasting knowledge, requires an approach that avoids cultural appropriation and promotes fairness to those that aid in this emergence from the Global South to the Global North (Ona et.al, 2021; Feeney and Labate, 2013)

Ludwik Fleck's insights into the relationship between the languages of 'hard' sciences and social sciences highlight the erasure of historical context in the production of scientific facts; a concern echoed in current discussions about the biomedicalisation of Ayahuasca. While many people have been able to attribute their ability to 'think otherwise' after a psychedelic experience, Ludwick Fleck attributes this ability to his nomadic status (Ludwik Fleck, 1979). As Fleck lived his life in Poland, Germany, Ukraine, and Russia and spoke these accompanying variety of languages, he came to some conclusions about his discovery of the relationship between the languages of 'hard' science (biology, chemistry, mathematics etc.) and social sciences (sociology, anthropology, ethnography etc.). Those conclusions included the idea that the production of scientific facts led to the erasure of the history surrounding it. Thus, with progress comes dismissal of work done previously.

To ensure epistemic justice regarding the influence of psychedelics across scientific fields, ongoing discussions and debates have emerged in the literature on the biomedicalisation of Ayahuasca, ignited by two highly regarded Brazilian scholars Eduardo Ekman Schenberg and Konstantin Gerber (2022). Drawing on neuroscience and constitutional law, they offered strategies which would honour and respect the Brazilian, Columbian, and Peruvian origin of the knowledge of the plant's resource and powerful uses within research and clinical practice. Although they do not address how these strategies directly impact PAT outcomes, they discuss how sources of epistemology are prioritised throughout the "diffusion of the sacred" and into the practice that will influence participant and patient understanding of their experiences (Schenberg and Gerber, 2022, pg. 611).

The debate over the biomedicalisation of psychedelics highlights the need for greater attention to justice and cultural competency. As such, scholars like Beatriz Labate and colleagues critique how Schenberg and Gerber overlook the "production of knowledge and the power relations attached to it" (Labate et.al, 2022, pg. 705). As an anthropological expert and advocate for the use of Brazil's Ayahuasca (DMT), Labate continues to accuse Schenberg and Gerber of committing additional injustices within their paper to inevitably "appeal to a Western audience" when addressing non-regulated forms of access to the sacred plant (Schenberg and Gerber, 2022). Where this can be avoided is through an exercise of reflexivity. This debate is an example of the depth and wide range of corrections that can be considered ongoing amendments to the discussion surrounding the biomedicalisation of psychedelics. It also prompts an ontological theorisation within this study that indicates how we evaluate our existence in a relative relationship with varying conceptualisations of the world. The relationship of such conceptualisations can include the intersecting histories that transcend global boundaries of the nature of the relationship of pharmacologically produced psychedelics relative to naturally occurring ones (Abena Dove Agyepoma Osseo-Asare, 2014).

2.4 Expectations

Expectations surrounding various forms of therapy have been thoroughly evaluated to understand their influence on treatment outcomes. In PAT, these expectations have been refined to explore the relationships between anticipated effects, blinding procedures, and the distinction between the placebo effect and the placebo response (Szigeti and Heifets, 2024 & Michiel van Elk and Fried, 2023). While most expectation analyses are held within economics, psychedelic research of measuring expectations begins with questionnaires such as the "Mystical Experience Questionnaire" (MEQ), "Altered State of Consciousness Questionnaire" (ASCQ) or "States of Consciousness Questionnaire" (SOCQ) (Carhart-Harris et.al, 2018; Younger et al., 2012; Roseman et.al, 2018 pg. 2).

The following discourse will consider the combination of implementing expectation guidelines in PAT and the increased presence of measurable coding frames to guide qualitative research. These questionnaires bring us to conclusions such as categorising sensations and identifying feelings such as "oceanic boundlessness (OBN)" that are profound in psilocybin treatments and reduce depressive symptoms (Roseman et.al, 2018, pg.2). Whereas the "dread of

ego dissolution(DED)" (Roseman et.al, 2018, pg.3) can be identified as an expectation or predicted orientation that lead to negative results in therapy outcomes (Cole-Turner, 2021). How we can influence the potential state of OBN or DED through guiding expectations in pre-sessions and containing them in post-sessions will increase the "subjective measures" of understanding human mystical experiences (Roseman et.al, 2018, pg.7).

Balázs Szigeti and Boris Heifets elaborate on the potential impact of patient expectations using a discourse analysis approach. They report that different types of expectations can significantly influence therapeutic outcomes across various medical interventions. This includes both positive expectations producing exacerbated positive results or producing mechanisms of disappointment with a correlative nature with negative expectations (vice versa). The authors also believe in management strategies for nondrug factors including two types of expectancy; stimulus expectancy (influenced by external stimuli and environment) and response expectancy ("self-confirming" optimism or pessimism toward the induced experiences of consumption) (Kirsch, 1999, pg.5). Their strength lies in suggesting multiple points of evaluation and viewing expectations as an independent control variable through its dynamic and relational components to placebos. This approach underscores the opportunities that can improve validity and consistent efficacy of PAT (Szigeti and Heifets, 2024).

Conversely, David Dupuis and Samual Veissiére (2022) suggest through a secondary qualitative analysis of articles that psychedelics, often heralded as a "therapeutic panacea," could instead be reconceptualised as "active super-placebos" (pg.571). Essentially, they believe the therapeutic processes of PAT increase the "suggestibility and influence extra-pharmacological, non-specific factors" (pg. 571) meaning information consumed prior to the intake will guide the experience and outcome based on the anticipated effects. Michiel van Elk and Fried (2023) offer suggestions of controlling that information by restricting the exposure to 'the hype' of psychedelics of their participants. Along with this not being necessarily possible to control due to new phenomenons such as 'the Pollan Effect' (causing a presumed magical cure rather than the understood mystical experience), it would contradict the efforts to promote exposure and reach diverse populations (Noorani, 2020). Psychedelics being a "super-placebo" demonstrate how knowledge dissemination to patients impact expectations, set and setting, and context –spiritual, clinical, licit, or recreational– in PAT.

While they include ethical and "epistemic integrity" that add immense support to the cultural competence of the discussion, Dupuis and Veissiére (2022) exaggerate that the mechanisms of placebo effect is greater than that of the psychedelic properties interrupting baseline neural activity. The exaggeration prompts a comparison of the evidential efficacy of the treatment to the (mediated or non-mediated) suggestive expectations contributing to treatment experiences (Hutten et al., 2024). The collision of the concepts of efficacy and expectations occurring in PAT is how Dupuis and Veissiére (2022) reached the understanding that these dynamics across various "sociocultural microclimates" (pg. 572) have received "little scientific attention and require further study" (pg. 573) a gap that this research aims to explore.

Henry Alice Westra et.al (2010) also believed "client expectancies remain among the most neglected of the common factors in psychotherapy and merit further research" (Westra et.al, 2010). At York University in Ontario, Canada, psychologists took to the collection of patient process expectations in cognitive-behavioural therapy (CBT). This was done by using qualitative one-to-one interviews with patient's posttreatment to invoke a retrospective exercise, reporting their expectations of the treatment and how they viewed the role of expectations in their results. Their aim was to compare and elaborate on the simple confirmation or "disconfirmation" of expectations prior to the CBT. Their method was unique among types of post treatment expectation measurements to understand "experience-expectancy concordance" (pg.444) due to the qualitative value, in comparison to quantitative expectancy questionnaires. The findings, which showed an equal distribution of overall positive and negative outcomes, revealed that unanticipated experiences significantly influenced which category participants fell into. This supports Wong and Raz's (2022) assertion that expectancy plays a crucial role in shaping evidence of altered states and personal improvement, thus making CBT expectancy evaluation relevant to PAT. They acknowledge this adheres to the decision affect theory which suggests that a contravention of expectations will result in significant disappointments while unexpected positive outcomes will be experienced as more pleasurable (Mellers et.al, 1997).

2.5 Goals of PAT

Understanding the goals of PAT requires an exploration of the essential components of set and setting, which, despite their informal origins, play a crucial role in shaping therapeutic outcomes. Three main goals of PAT that are identified through a collection of researchers:

deprescribing medications, addressing treatment resistant patients, and tackling addiction (Carhart-Harris et al., 2016, Carhart-Harris and Goodwin, 2017, Pollan, 2018). These three goals are collective in finding gaps in niche appointments of mental health. Balancing the recognition of adverse effects is vital for the reception of information to the wider population that will determine the success of the renaissance or 'third wave' of psychedelic integration (Austin, 2017).

A key component to be understood in this biomedicalisation of PAT—with lack of concrete etymology yet incredible property— is set and setting. While some can trace the application of this term to PAT to Timothy Leary, Ido Hartogsohn (2022) conceptualised set and setting as fundamental and inherent aspects of PAT that reveal the deep connections between its traditional use and its current application in research and biomedical clinical practice. Set would be how the intention, expectations, down to the personality of the patient and clinician determining what the journey about to be produced by the dosage and identification of psychedelic will produce (Zinberg, 1984). The setting components include the different type of environments of temperature, lighting, clinical, naturalistic (cultural setting), sound/music and emphasising safety confidence. The highlighted importance of understanding set and setting supports why the medicine is better consumed in a controlled constructivist therapeutic intervention, considering variables such as "the nature of knowledge, problem definition, treatment goals, assessment, [and] treatment of emotion" (Granvold, 1996, pg.1).

Chapter 3: Methods

This chapter will detail how a qualitative research method was developed to address the RQ. Starting with obtaining ethical clearance, constructing a topic guide, conducting semi-structured interviews after recruiting from a population within the inclusion criteria, and finally, analysing and coding the information provided by the participants. The research method was deployed to examine the application of epistemology to PAT, which in this context refers to the study of knowledge systems that support and influence how clinicians and patients understand the practice. Additionally, the method aimed to utilise reflexivity—a practice of critically reflecting on one's own biases and assumptions—as a qualitative tool within the theoretical framework (Collins and Stockton, 2018).

3.1 Qualitative Research Methods

The research method uses primary qualitative data obtained from one-to-one interviews. It provoked inductive and retrospective recollections and reasonings from participants, due to the observational nature of responses, to draw conclusions and to ensure the methodological coherence of the research (Flick, 2022). Methodological coherence best represents the alignment of exploring a phenomenon –epistemology-- that which little is known and reported (McLeod, 2001). The primary research method using semi-structured interviews was chosen over other theoretical method options due to the observational component used and prompted through the topic guide (Flick, 2022). The semi-structure allows reports of previous background or exposure to psychedelics and the shifts involved in anticipated feelings towards the therapy to be discussed with fluidity throughout the discussions. For a desired individual engagement and expertise, the one-to-one interview was chosen over other qualitative research methods such as focus groups or ethnographic research. An open coding process allowed for the conversation to be led by the expertise held within the conversation, being in the hands of the participants. This was then sorted through coding to find common themes and aspects of therapy to address the aims of the research.

3.2 Recruitment

The recruitment method began with identifying participants through the roster of researchers at King's and Imperial College London that engaged in past and ongoing psychedelic-assisted therapy studies. Recruitment was conducted via direct communication facilitated by departmental resources, including the Education Support Team, the King's Clinical Trials Unit, Imperial College Consultants and consensual referred contacts. The method of correspondence was via Outlook emailing that prompted the reasoning the participant was being contacted and a brief outline of the study.

3.3 Sampling

A purposive sampling strategy was deployed as it was conducive upon the components of the inclusion criteria and of the RQ and sub questions. The inclusion criteria for this research encompassed individuals who identify as clinical trial researchers, practising psychotherapists, or postgraduate students involved in PAT. This ranged from those at King's College London's Institute of Psychiatry, Psychology, and Neuroscience (IOPPN) and those a part of the Center for

Psychedelic Research at Imperial College London (Imperial College London, 2021; King's College London, 2024). Additionally, the study also includes psychotherapists that are currently practising PAT legally in the United States in controlled clinical settings. This research incorporated a diverse cohort, including individuals of various ages, genders, and educational backgrounds. Their personal information is anonymised while their identities are represented as numbers when discussing the findings. The desired sample size was scaled upon the amount of time requested and created for the interviews. For thirty-five to forty-minute one-to-one semi-structured interviews, 7 participants consented to engage in conversation to share the information (Westra et al., 2010). Their demographics are shown below.

i. Table 1: Participant Demographics

Participant	Position	Gender	Years of experience in Psychedelics
1	Psychotherapist	M	6
2	Psychotherapist	F	~6
3	Medical Psychology Student	M	4
4	Psychiatrist	F	7
5	Psychedelic Research Therapist	F	7
6	Clinical Psychologist + Psychotherapist	F	~3
7	Neuroscientist PhD Candidate	M	7

3.4 Topic Guide Rationale:

The topic guide was designed to explore the epistemic influence on expectations impacting outcomes of PAT. The guide is structured around five key topics: Participants Education and Previous Exposure to Psychedelics, Practical Clinical Involvement, Participant Briefing, Clinical Observations, Fundamental Reflexivity for the Future of PAT.

The structure was influenced by previous literature indicating the importance of researchers understanding the combination of ontology and ethical considerations forming the "assumptive worlds" of their participants (Dupuis and Veissiére, 2022, pg. 575). The topic guide reveals how I explore this combination as a researcher, while prompting my participants to explain how they do the same in their research of PAT. Exploration of the individual's expertise, epistemological influences, and relevant experience in practising research and clinically led PATs was conducted. Reflection of how and what my participants engage with or contribute to the preparatory information provided to their patients is explored in the second and third key topics to provide insight into how their individual ideologies of the practice impact the therapeutic process (Mayan, 2009). The following key topics allow interactions and observations made by the participants to be reported along with how their perceptions of patient expectations impact the study. Further questions explored how alignment between experience and expectations affects their research (Kirsch, 1999).

3.5 Data collection and management

The method of data collection involved the use of a topic guide (outlined above) during thirty five-forty minute semi-structured online interviews. The recordings and transcripts of the interviews (n=7) were captured via Microsoft Teams transcription tool, as well as with the iPhone transcription application *Otter*; to ensure accurate documentation. After the completion of data collection, the interview transcripts were refined to verbatim clean before being stored in a personal OneDrive KCL University account. Assurance of anonymity throughout the documented conversations was done by assigning numbers to each participant along with redacting any personal identifying information. These refined, anonymised transcripts of the interviews were printed to hard copies that were used for coding purposes that were later properly disposed of. To aid in the process of coding, *Nvivo* software was used. The collection of interviews and other recordings will be removed from the secure OneDrive after the submission of this dissertation fulfilment.

3.6 Data Analysis

To address the RQ, thematic analysis was used to evaluate the collection of data. Themes were developed from participant responses to create a cohesive data set. The inductive method of Consensual Qualitative Research (CQR Hill, Thompson and Williams 1997) was used as a

framework to first divide the interview transcripts into domains. Then the main ideas of these domains were identified leading to a cross analysis for comparison. Virginia Braun and Victoria Clarke's six steps of reflexive thematic analysis (RTA) were used under the CQR framework for a more detailed methodology. First familiarisation of coding occurred via creating verbatim clean copies. Then, once the transcripts were reviewed again to generate initial codes, the search and review of tentative themes were established. Finally, categories to describe the domains and define the themes were written. Establishing themes was possible by displaying coherence throughout the results, using consistency across each data set, and ensuring this sample could be replicated (Hartogsohn, 2017). This process ultimately builds towards addressing an ontological relationship with the nature of being in an ineffable ASC that can be impacted by what is known prior to entering such ASC(Mayan, 2009). By incorporating both primary and secondary/interpretive reflexive exercises, the thematic analysis was constructed.

3.7 Ethics

This study adheres to the minimal ethics risk standards set by King's College London for the Global Health and Social Medicine department (Clearance Reference Number: MRSU-23/24-43526). Throughout the study, crucial aspects of informed consent, confidentiality, and research integrity were maintained, ensuring accurate representation and interpretation. Review of the information sheet in Appendix i and completion of the consent form in Appendix ii was mandatory for all participants. This outlined participants' expectations, roles, privacy rights, and withdrawal options throughout their involvement. Participant identities were protected in accordance with minimal risk assessment guidelines by ensuring anonymity by excluding personal information from publication. Detailed data management procedures adhering to the required ethical standards are provided. While these conversations involved substances that are, in some instances, considered illegal, no condemning information was asked to be shared. By avoiding inquiries into illicit psychedelic practices on the subject and instead seeking academic focused feedback, the topic guide effectively minimises discomfort and the recall of sensitive information.

Chapter 4: Results

In this chapter, the themes and further subcategories are reported. The themes are: Converging Knowledge Dynamics, the Influence of Set and Setting, and the Assessments of Future Orientations. The results are presented through descriptions and examples formulated through epistemological concepts expressed in the semi-structured interviews.

Theme 1: Converging Knowledge Dynamics

The collection of knowledge foundations held in the research of PAT between the participants and clients includes academic therapeutic training, preparatory information, popular media sources, and experiential learning. These sources ultimately build upon the agents' empirical and rationalist knowledge that influence the expectations of people engaging in PAT, further shaping the therapeutic process. Most participants spoke about how their engagement of knowledge dissemination to clients, compliments the therapy's ethical standards including the client's ability to provide fully informed consent.

4.1 Prioritising fully informed consent

The utmost importance to all participants was recognising that the trust and full consent of patients was obtained. This was mentioned frequently as the integration sessions are "really just about getting them to a place where they can fully consent" (P.2). The participants' diversity of roles provided insight into where and at what stages of the therapy expectations are being considered and influenced. For example, P.3 said her role as a medic "involves doing the screening, so when they come in making sure they're eligible, making sure they understand what it involves or what to expect and taking the consent". Whereas P.1's role as a psychotherapist spoke further to the psychological shifts such as "in large doses sometimes, these things lead to a, what they call an 'ego dissolution' and if you've never had that, it's hard to imagine it". He continued to say that preparatory information is thorough because "there's an ethical question about whether or not you can really prepare people for fully informed consent". The extent of this preparatory information impacting expectations more than other sources of information was not able to be measured in this dissertation.

The process of obtaining fully informed consent induced some shifts of expectations concerning the environment. For example, P.2 says it's important for them to "know what it is that they are signing up for, because some people come with an idea of wanting a natural medicine, for instance". This participant explained that their duty as a researcher and psychotherapist was to be honest in both the "acknowledgement that there is a long standing legacy of using these substances in that holistic environment" while being transparent that "what they're getting is not that". Rather than a 'natural medicine' what they are being offered is a pharmacologically compounded psychotropic substance in a controlled clinical setting.

Obtaining consent to use synthetic drugs is important when encountering patients that prefer natural medicinal remedies, especially if that serves to support their personal identity.

4.2 Common Sources of Client Knowledge

It was important for the participants to learn about their client knowledge to establish trust among all the agents within the therapy, including the psychedelic. The participants work in conversation with their client to "see what they already know, or what their kind of ideas already are about it, and try to fill in the gaps" (P.4). The participants suggest that bridging the knowledge gaps is akin to preparing for therapy, which they describe as "quite tricky" due to the challenge of defining the "ineffable experience" (P.3).

Over 70% (5/7) of my participants reported that their clients' knowledge about psychedelic experiences were based specifically on documentaries (Netflix's *Magic Medicine*), books (Michael Pollan's *How to Change Your Mind* and Merlin Sheldrake's *Entangled* Life), and other popular media sources. The self-exploration of clients was not explicitly discouraged. However, P.1 explained that "what happens is that an awful lot of these people have also been on YouTube, because you can't really stop them", indicating, it may be better if you could 'really stop them' from consuming mass amounts of information from unverified sources. The mention of the popular media sources were accompanied with references to prior studies reporting "the media and the hype will sustain about five years worth of additional kind of expectation bias, which then, when that drops, the efficacy of the drug drops, after about five years" (P.2). The inclusion of previous data and the frequent references to similar sources demonstrated that participants believed media sources helped formed the basis of the expectations clients brought into the research. Other assessments of client expectations from at least four of my participants

explicitly stated the status of being a "psychonaut" (P.7) "is going to influence their expectations on what's going to happen" (P.5). Assessing what their clients know came after the participants' own reflection of their knowledge backgrounds and other contextual factors influencing their roles as guides.

4.3 Reflexivity of Participant Knowledge

Reflection on each participant's epistemic frameworks –shaped from their education and therapeutic training– highlights how these rationalist academic frameworks influence their therapeutic engagement. This reflection evaluates their capacity to acknowledge what they don't know and trace the origins of what they do know. Participant 4 provides an example of fluctuating opinions and feelings toward the therapy by saying, "the more experiential knowledge I have and reflecting on when I first started working, I probably had more... I'm still enthusiastic about it, but I find it may be a bit more skewed". Further experience with clients expands the participants' empirical knowledge–learning by doing. She discovered her attitude of the therapeutic process became adversely biassed after observing poor therapeutic outcomes.

Despite almost all participants lacking "formal education" (P.3) on psychedelics in their curriculum, their diverse backgrounds in therapeutic and medical training highlight varying levels of expertise of PAT. While some participants had additional training that was more "psychiatric in nature rather than to do with psychedelics" (P.4), another said they and their team had to undergo "trial specific rather than generic training" (P.1). However, P.6 who is legally practising in the United States has a collection of Master's and Doctorates in different types of counselling including Integrative Psychiatry Institute - Psychedelic Therapy Training.

Other outstanding learning opportunities were found by P2 and P7 who began their analyses of psychedelic administration in different settings of South America and various European countries that were practising plant medicines. This type of knowledge was obtained via observations. When asked about bringing their observational knowledge into clinical settings, one stated that it was "not my place" (P.2). This phrase was used to describe their separation from guiding in Indigenous settings and to clarify that they did not impose their exposure of Shamanic methods in clinical environments.

Theme 2: Influence of Set and Setting

Acknowledgement of diverse and existential identities held by the agents of PAT, impacts the intentions *set* to explore ASC. Integrating the psychedelic's identity and its Indigenous historical context into modern medicine is a part of the process of acceptance. All participants also attribute the essential and careful elements of set and setting –such as music and spiritual exploration– in PAT to Indigenous practices.

4.4 Indigenous practices being replicated in therapy

The exploration of elements of set and setting revealed a distinct theme where participants discussed the incorporation or omission of Indigenous practices in their clinical work. Most (5 out of 7) participants acknowledged that "the psychedelic therapy field would not exist if it weren't for Indigenous folks who have been using psychedelic substances for centuries, and have been willing to share their practices with folks in the Western world" (P.6). When asked about respecting Indigenous knowledge in PAT clinical trials, nearly all expressed a commitment to addressing cultural and historical contexts. To establish a respectful acknowledgement that "there are many things in the way that set and setting work in a clinical trial that have some of the hallmarks of more Indigenous practices" (P.2), most of the participants try to 'root' their preparatory sessions "in nature and Indigenous tradition and then talk about the scientific [aspects]" (P.5).

However, when discussing the integration of Indigenous practices within modern psychedelic research, there is a tendency to prioritise recent data over historical context. As P.2 points out, it is considered more relevant to biomedicalisation and valid to the research community. Furthermore, the incorporation of Indigenous context varies for each substance, as P.1 notes that external factors like sponsors and protocols influence the "flavour and culture" surrounding each substance. Different research institutions support and project objectives that will be more influenced by Western medicine, monetisation, and integration through policy. The 'flavour and culture' shifts when other research institutions prioritise sharing the value of research outcomes with diverse communities. Both P.7 and P.2 admit that Indigenous influence should be used sparingly as to not over-exploit the tradition and to maintain a Western protocol to what is accepted as valid literature in modern medicine.

4.5 Safety Assurance

When discussing how participants conveyed the origins and historical use of psychedelics to their clients, the conversation emphasised using the long history of safe use to address patient

safety concerns. Years of traditional use ensured physiological safety for patients concerned about physical adverse effects. Participants said physiological and psychological safety is assured through levels of trust established in preparatory sessions with their clients. P.1 summarises what most participants prioritise when assisting this entry "into quite altered states" which is to "trust them to find their own way, to trust their body, to trust their senses to, to do what feels healthy and within some basic safety parameters". Establishing "pillars of trust" fostered assurance between trusting the guides and therapist, trusting themselves, and "trusting the drug" (P.7). The three pillars of trust brought agentive characteristics to themselves, the therapist and the drug. The trust established is not solely for the client to trust the researcher but for the trust to be mutual as P.6 says, "you feel so completely high, it's like your energies are matched and you are in this wave with them". The excerpt from P.6 suggests that a client's feelings significantly influence the participants' perception of the therapeutic process. A reciprocal dynamic is created by this "wave" of energy where participants' perceptions mutually affect the client's feelings about therapy. This shared sentiment can also be viewed as the 'set' of the therapeutic space, where expectations are categorised.

Participants also help clients understand that the psychedelic components used in the trials and therapy have been pharmacologically composed and "synthesised in the lab in Switzerland, so it's got a very different vibe to it"(P.1). The synthetic measurements assure consistency for the clients and the research, creating an appropriate clinical space where the participants are not expected to act as shamans. Rather, the practice is "pseudo therapeutic kind of types of ceremonies" with frameworks of comfort for both participants and clients (P.7). To address client's safety concerns, P.2 said, "a lot of the work in trying to support people with unreasonable expectations, is not just as important for scientific evidence, but it is also for safety". Emphasising it has been a practice for centuries also shows that participants place effort into comforting patients with any elaborate anticipations of fear.

4.6 Participant and Client Identities

The identities of the participants and clients contributed highly to the discussion of cultural competence present in PAT practices. To highlight the cultural significance of the identities of clients and guides, certain measures were taken. Accommodating a clients preferences of the researchers' identity to "match up with their kind of reference systems so that you can partly create rapport but also so that you can be most effective in sort of supporting them

through the experience" were examples of such measures (P.1). The progress of PAT "to expand the kind of demographics in terms of age, sex, and ethnicity" (P.4) of both researchers and clients is a demonstration of the efforts made to "understand the idea of how an expectation is going to have cultural differences" (P.3).

Two participants held opposing views with regards to how cultural identities impact therapy. Where P.6 believed "if people are completely atheist and people have no interest in that spiritual component, they do not get as much out of it". Whereas, P.5 took to understand that if a person's religious affiliation is agnostic or atheist they are still "able to access that mystical like experience without having a particular religious or spiritual preconception". Having a foundational faith system or varying existential values may cause clients to anticipate encountering their image of a higher power, thus shaping the therapeutic process.

Theme 3: Future Orientation Assessments

The participants and clients' future orientations regarding hope, anticipation, and fear of entering an ASC contribute to the ethical considerations and validity of the biomedicalisation of PAT. The factorial contributions include examining the impact of double-blind and placebo conditions (current necessary components of therapeutic research) as well as their impact on the therapeutic environment and participant expectations (Michiel van Elk and Fried, 2023). Many participants were confident in speaking to client expectations to the same extent as explaining their own expectations. Their confidence to do so originates from their experiential and therapeutic practice to assess their patients where examples are provided below.

4.7 Participant Expectations of Therapeutic Process

The expectations held by PAT guides (including my participants) of the therapeutic process and improvement of client's mental health, is believed to hold a significant place in PAT. P.5 used an example of members within her team holding different expectations when the study was not a double blind. Her colleague used to take "a really laid back approach to the placebo session" until a placebo session she assisted on proved to have "very impactful visuals and insights" for the client (P.5). When the researcher knows the active status of the substance their client is receiving, their entry into the 'space' can have different approaches which impacts the integrity of the research and the understanding of the strengths of placebo in PAT.

Other admissions of personal expectations of the therapy from participants include naivety in both positive and negative regards. Some participants acknowledge that they still "didn't know what to expect, I mean I knew clinically and I knew through research what to expect" (P.6). The naivety can suggest that some participants find it beneficial to enter the space in the same way they instruct their clients: to "attend to whatever happens, don't try and make something happen or don't try and stop anything from happening" (P.1).

4.8 Participants Assessment of Client Expectations

The assessment of all expectations brought into the therapeutic space begins with understanding and mediating what the client knows about PAT; as seen in the previous sub theme of 'common sources of client knowledge'. A recurring assessment of client expectations recalled their client stating things such as "I know it's not a magic pill" (P5). However, my participants reported that their therapeutic training allowed them to conclude that their clients' expectations were otherwise by "the way they orient (themselves) to the medicine, it is like a magic pill" (P.5). This idea was positioned by P.1 stating "they want to experience, the dosing day, to be the day where that produces this kind of Miraculous Wand of 'I'm not depressed anymore'". These types of more radical expectations are ones that adhere to the decision affect theory by likely cause feelings of disappointment when they are not met.

Reducing or "disabusing them [clients]"(P.1) of false perceptions of the therapy was an important role for my participants. Understanding it's not magic or being conducted in "the jungle or something"(P.1), were also false expectations of clients. The participants would assure their clients that it is a clinical setting made to make them feel comfortable. Once clients understood the therapeutic setting, participants observed a shift of expectations from magical to medicinal aims.

4.9 Evaluating Therapeutic Outcomes

Post-treatment evaluations of expectations are typically carried out through questionnaires, highlighting the absence of post-treatment qualitative evaluation of expectations. However, comprehensive assessments of whether the key anticipated outcomes of the therapeutic method were achieved are essential for understanding subsequent responses and informing future regulatory strategies. Since quantitative questionnaires are employed by other members of the research team, "the therapists aren't doing much of the actual data recording of things like change" (P3). The lack of comparing pre-treatment and post-treatment expectations within

research methods represents an inconsistency with evaluating and reporting influential 'set' variables. Amending the post-treatment collection of satisfaction of the therapy rather than "occasional checking in on symptoms, side effects, adverse effects" (P3) would address this inconsistency.

Research Research Question: How do epistemic value systems within the biomedicalization of psychedelic-assisted therapy (PAT) shape the expectations of mental health treatment?

Sub Questions: What are the phenomenological expectations or assumptions influencing the outcomes of PAT from the perspectives of researchers and therapists? How can cultural competence be integrated into the biomedicalization of PAT to enhance its efficacy and effectiveness?

Theme	Sub-Themes /	Example (quotation or text reference)	Theme Description
	Codes		
Theme 1 Converging Knowledge Dynamics	Prioritising fully informed consent to the priority of the pri	, , ,	
	Code 1B Common Sources of Client Knowledge	screening. 'What do you know already' and people say, 'well, I watched this documentary on YouTube, I watched this Netflix thing, I read Michael Pollan's book'.	Evaluating the credibility and representations of the sources of knowledge, including popular media, is essential for understanding how they influence perceptions of psychedelic experiences, potential benefits and

			risks, and the historical context surrounding their use.
	Code 1C Reflexivity of Participant Knowledge	"Just doing my own personal work around like what are the implicit biases that I have around the participant that I'm sitting in front of? What misconceptions? Am I still, you know, being open to the medicine or have I shut myself off and think I'm an expert and I know everything" (P.5)	Reflecting on participants' epistemic frameworks from their education and training reveals how these shape their therapeutic engagement and their awareness of knowledge gaps.
Theme 2	Code 2A	"More sort of shamanic practices like the	The interplay of
I., fl		use of music, the ideas around reflections on	biomedicalization of a traditional
Influence of Set		later but there are many things in the way	practice highlights the integration
and Setting			of Indigenous wisdom within a
		that have some of the hallmarks I think	modern medicinal context,
	replicated in therapy	more Indigenous practices and thinking about the environment" (P2)	creating a
	therapy		therapeutic environment that
			respects and draws upon its
			cultural origins.
	Code 2B Participant and	"Who you are and how you show up energetically, emotionally, absolutely, is going to influence what can be co-created in the space" (P5)	Acknowledging the different spiritual or religious associations, sexual orientations, race, identities and overall culturally
	Client Identities		significant backgrounds are brought into the space, impacts a vital aspect of openness of PAT.

	Code 2C Safety Assurance	"we do talk about how these compounds have been used in Indigenous communities safely for hundreds if not thousands of years" (P.1)	The significance of clients' comprehension of safety is highlighted by the recognition that, while the setting is clinical, the atmosphere is deeply informed by foundationally reliable Indigenous practices.
Theme 3 Future Orientation Assessments	Code 3A Participant Expectations	"You know what we're quite enthusiastic period and we're trying to keep that measured, so that we're not, you know, sort of disrupting the kind of data too much" (P.1)	The role of participants as active contributors within the therapeutic process is crucial in shaping expectations regarding the biomedicalization of PAT.
	Assessment of	"It's often that I will kind of speak to the participant, see what they already know or what they're kind of ideas are already about it. And then try to fill in gaps or to maybe if you know if there's any kind of misunderstanding or kind of meet them where they are and try to find ways in which to explain things to them that will make sense" (P.4)	The unspoken or interpretive anticipated feelings towards what will be experienced in the therapeutic session includes feelings of hope and at times unreasonable expectations of journeys and mental health status outcomes.

(Code 3C		Assessments of mental health
	Evaluating Therapeutic	they do well on ketamine. Somebody who's having tons of panic attacks, and it's a physiological response, sometimes makes it worse." (P.6)	changes were reported over comparing original expectations to therapeutic outcomes. My participants were not a part of utilising quantitative methods to measure degree of expectation satisfaction.

ii. Table 2: Presentation of themes, sub-themes and examples found within interviews to establish the themes.

Chapter 5: Discussion

The research question prompting the discussion in this dissertation is: how do epistemic value systems within the biomedicalisation of PAT shape the expectations of mental health treatment? The main findings emphasise how the combination of epistemic value systems held by the agents of PAT –the client, researcher, and psychedelic itself—influence expectations of the therapeutic process. Moreover, how their identities contribute to their individual value systems. Finally, how the assessment of expectations shaped by epistemic considerations is inconsistent. The critical analysis of the findings and how they impact psychedelic research will ultimately represent the collision of all themes toward common improvements. Contributing to the themes are frameworks of epistemology, including epistemic authority, rationalism provoked by educational systems, personal existentialism influencing the set of PAT, and empiricism aiding in our understanding of the expectations in PAT (Goertz and Mahoney, 2012).

5.1 Converging Knowledge Dynamics

The aim of this research was to understand how the construction of expectations through knowledge systems, held by agents of PAT, impacts the overall therapeutic process. The aim directed my analysis towards understanding the clinicians' and clients' epistemic values of empiricism and rationalism, offering insight into the construction of expectations of PAT.

The theme of converging knowledge dynamics addresses who holds the epistemic authority within PAT (Cole-Turner, 2021). The therapy professionals that make up the participant population hold expert knowledge. The majority of valued education through rationalism is from Western foundations, yet was inspired by self-exploration, interest, or "divine-led" (P5). Whereas their clients hold what can be identified as lay knowledge, was primarily obtained from popular media sources (Arskey, 1994). Epistemic authority was conferred to both agents through the optimal collaboration of the two knowledge dynamics. Participants indicated that while they act as guides to correct paths of misconceptions and apply their therapeutic expertise (Houot, 2019) epistemic authority is shared with clients –as this practice involves exploring the client's minds. Adapting characteristics of an epistemological form of constructivist therapy that involves assessing the client's "nature of knowledge" and "treatment of emotion" offers support to the clients epistemic authority and overall set and setting of PAT (Granvold, 1996, pg.1).

Shared epistemic authority is beneficial to maximise the integrity of therapeutic research. From a sociological perspective, "medical practitioners have been required to be more clearly and openly accountable to lay assessment and more sensitive to patient viewpoints" for reasons including fully informed consent and to explore different facets of the research (Prior, 2003, pg. 42). The current literature does not offer substantial suggestions to remove the concern of fully informed consent to an ineffable experience. However, sharing epistemic authority provides a framework for collaborative decision-making that can enhance trust and transparency in the therapeutic process. (Carhart-Harris et al., 2018; Hutten et al., 2024). The additional facets include variables within the 'set' of PAT such as expectations. Participants more commonly redirected patient expectations to a collected intention or shared understanding of the goal of the therapy. The participants that emphasised engaging in this exercise were more strongly noted in their therapeutic behaviour, sensitivity and language in the interviews. While these therapeutic qualities are assessed to be necessary to ignite collaboration among the agents of PAT, the process of doing so was seen as inconsistent and unregulated. Further structure surrounding the regulation of expectations may increase the therapeutic research's integrity.

5.2 Influence of Set and Setting

Essential components of set and setting transcending to all psychedelic practices from the origin of psychedelic use is influential with to the efficacy of the practice being carried out today. The participants believe the culture around the psychedelic substances they work with, invites an essential variety of context to the set (mental state) and setting (physical and socially influenced environment) of PAT. The context would include a conducive atmosphere and the identities of the psychedelic, the participants themselves and more importantly their clients, adding to the modalities of set and setting (Hartsogen, 2022). The results support that the vast modalities created a double movement; the expectations (which are part of the 'set') influence the conditions (set and setting) under which the therapy is conducted, and simultaneously, the set and setting themselves shape the expectations.

The evaluation of the epistemological foundations each agent brings to PAT, including their spiritual beliefs and personal identities, reveals a complex interplay between cultural perspectives and the therapeutic process. Divergent views among participants about the role of cultural and existentialism-based beliefs indicate that a one-size-fits-all approach is inadequate

for understanding the interplay. Metaphysical beliefs produce a form of epistemic humility to the agents of PAT, encouraging an understanding that the experience is filtered by the individual (Matvey and Kelley, 2022). Previous research suggests that "psychedelics disrupt functioning at a level of the system...that encodes the precision of priors, beliefs, or assumptions" (Carhart-Harris and Friston, 2019, pg. 320). However, rather than psychedelics altering prior beliefs or assumptions, the findings support the idea that these beliefs and assumptions influence the therapeutic intention and the overall 'set' of the therapy.

Ludwik Fleck's argument that "knowledge is not dependent on the social group, status, or aspiration of people who produce this knowledge" (Fleck, 1979) contrasts with the suggestion that the effects of psychedelics are shaped by social and cultural variables (Hartogsohn, 2017). If knowledge is indeed independent of such social factors, then why do the effects of psychedelics appear to depend on them? As we continue to explore how 'set and setting' influence drug effects, the focus should shift towards constructing more precise parameters of control, beyond simply managing expectations or controlling the "hype" around psychedelic substances (Michiel van Elk and Fried, 2023). By doing so, we may begin to understand how expectations function as control variables, thereby refining therapeutic approaches to align more closely with the diverse epistemological landscapes of both clients and practitioners. To provide comparative context, Indigenous communities rely on traditional norms to protect their societies in psychedelic practices (Sanabria and Talin, 2017). In contrast, incorporating additional ethical frameworks to guide client expectations in Western medicine can exemplify comparable concerns of protecting psychedelic practices.

The representation of identities through the voices and attitudes of the agents of PAT are influential to the therapeutic process. The integrity of researchers and guides is reliant on safeguarding clients' identity, especially in states "of extreme suggestibility" (Dupuis and Veissiére, 2022 pg. 576). This concept of safeguarding the identity of psychedelics and its historical epistemic value are not replicated. The participants who obtained a naturalistic educational background expressed their personal appreciation for Indigenous influence of set and setting but met that appreciation with hesitations that further adoption would cause appropriation of the "object of knowledge" (Schenberg and Gerber, 2022, pg.614)

However, the integration of these practices into modern research remains selective and not in the hands of the participants in this dissertation. Rather, participants noted a tendency to prioritise recent data over historical context, viewing contemporary scientific findings as more relevant to biomedicalisation and more valid within the research community. This selective incorporation raises important ethical questions about the extent to which Indigenous practices should be included in Western therapeutic models. The identity and professional role of who is going to argue for Indigenous contribution and acknowledgement remains unknown.

5.3 Assessment of Future Orientations

This theme was instrumental in understanding how the RQ is structured around the therapy process rather than its outcomes. Participants focused the conversation on the process or 'journey,' which can be explored through the research method and its results. The results differ from previous studies examining effects of expectancy because the participants did not provide post-treatment information to compare the expectations prior to the treatment.

The anticipated feelings, specifically, response expectancy (Szigeti and Heifets, 2024), regarding what may be experienced in an ASC, can be variables to predict the individual processes of PAT. The extent to which this claim was addressed in this dissertation revolves significantly around the previous experiences and empiricism held by both researchers and clients. Clients' prior use of psychedelics, and researchers' experiences from earlier clinical sessions, play a key role in shaping these expectations. For clients, having prior experience with psychedelics may necessitate a shift in their intention from recreational to medicinal use. For researchers, clinical observations and practices are affected by the knowledge of the placebo placement. The intentional use of double-blind mechanisms must be employed to prevent biases that could influence their guiding behaviour during therapy sessions (Szigeti and Heifets, 2024). Furthermore, I would alter the possibility of clients being in a null placebo group overall. Replacing the placebo with an active placebo (smaller or microdose) would avoid diminishing psychedelics to a "super-placebo" (Dupuis and Veissiére, 2022, pg.571), mitigating reports of disappointment, remove outstanding ideas of what depth of ASC they may experience and ensure equal engagement from the participants.

Assessing the information that shapes the expectations impacting the process of the therapy led to concluding that the preparatory sessions are highly impactful in both correcting misconceptions (Houot, 2019) and providing concrete anticipatory effects to the experience of the therapy. Younger et.al (2019) advises "the need to measure patient expectancies [to] be

particularly important in the context of clinical trials" (pg. 768), especially one that can be difficult to describe the effects of the medicine. In the preparatory process of describing the potential effects of ASC to obtain fully informed consent, client's expectations may begin to adhere to those potential effects. One participant spoke about an experience their client had containing full visuals, imagery and sensations during their experience in a stimulated (placebo) ASC. I suggest expectations be measured qualitatively at multiple stages of the research including prior to preparatory sessions, immediately prior to the psychedelic intake, and post intake to confirm if the information that is given to obtain fully informed consent influenced their client expectations over other sources of information. Qualitative measures –over utilisation of the MEQ, ASCQ and SOCQ— would address the inherent "flaw in biomedical discourse of epistemic authority, which is based on supposed precision and quantification" (Schenberg and Gerber, 2022, pg. 614).

5.4 Limitations

The limitations of this study include the diversity among participants, both in terms of the client populations they served and the range of epistemic sources they were exposed to, particularly concerning Indigenous practices and shamans. Incorporating Indigenous voices in the dissertation would both adhere to suggestions made by Labate et.al, Schenberg and Gerber, and Feeney and provide strength behind arguing for further representation in clinical spaces. However, if such perspectives were included, they would continue to provide third-degree reporting of their assessments of client/patient expectations. The degree of perspective highlights the complex navigation of truth throughout the renaissance era of psychedelic research.

The claims of truth seem to shift among agents as shown through examples in the subtheme *Participants Assessment of Client Expectations*. Participants expressed they must navigate the truth of the clients' expectations without having explicit tools to do so. Interviewing clients of clinical trials and patients of clinical practice would bring a comparative value to the results of this dissertation. This would also construct a more thorough evaluation of different classifications of knowledge systems.

Chapter 6: Conclusion

The previous chapters started with an introduction to the myriad of disciplines contributing to psychedelics. The second chapter reviewed the synopsis available among debates,

previous research and other analytical literature surrounding psychedelics and their course of biomedicalisation. The third chapter reviewed the methods deployed to answer the RQ; including an epistemological approach to qualitative data collection via one-to-one semi-structured interviews. The significant excerpts from the interviews were provided with how they support the aims of the research in the results chapter. The discussion chapter discussed how the experience reported by the participants can be utilised to further develop PAT with the support of knowledge dissemination. This chapter will reiterate epistemological frameworks brought into this dissertation to enlighten what sources of knowledge, belief systems, and priority educational structures are influencing the expectations of the process of PAT. Finally, this dissertation will end with posing further questions to engage the myriad of disciplines PAT encompasses.

A key conclusion of this research is that the expectations of all agents involved in psychedelic-assisted therapy (PAT)—including participants, clients, and the psychedelic substance itself—intersect and influence the therapeutic process. This highlights the crucial role of managing expectations in conjunction with the administration of psychedelic medicines to have 'peak' experiences. The identities of each agent along with the epistemic values brought into medicine by traditional practice represents how cultural influence impacts the set and setting of PAT.

By integrating frameworks of epistemology—including epistemic authority, rationalism, existentialism, and empiricism—this research offers valuable insights into how expectations are constructed and managed within PAT, ultimately contributing to the ongoing development of more effective and ethically sound therapeutic practices. A combination of the epistemological foundations of Indigenous practice and clinical research practice from over the centuries should be utilised to guide both patient response and stimulus expectations as a variable in PAT in non-exploitative measures. The combination of epistemological foundations show how empirical teaching used to share the history and Shamanic traditional practice is mirrored in experiential development for agents in clinical PAT. The traditional practices have been rooted in Western academia since the 1960's which developed the available rationalist knowledge frameworks of the clinicians. Finally, the existential presence inherent in Indigenous practices, gives insight to the modalities to set and setting including intentions, response and stimulus expectancies, and how we assess our existence in relation to different (spiritual) conceptualizations of the world (Kirsch, 1999).

I will conclude with an essential part of a RTA practice; that is to ask more questions. As Jacob Bronowski says "That is the essence of science: ask an impertinent question, and you are on your way to a pertinent answer" (Carhart-Harris and Goodwin, 2017, pg. 2107). While recognising this approach is unique to other therapeutic designs, with additional barriers to overcome, the important questions are those of reflexivity: Will this panacea-ideologic mental health remedy mitigate unrealistic expectations or increase them? Would an implementation of prescriptive qualitative questions create a space where structure works negatively to the autonomy of the agents and provides damaging restrictions for psychotherapists and guides? Would this be further 'divorcing' the practice from Indigenous use for the sake of science? Or are these the types of additions needed to recognise the Western neo-shamanic era we are entering? What would our world look like if everyone tried different forms of PAT? (Pollan, 2020).

Appendices:

Appendix ii: Information Sheet Appendix ii: Consent Form Appendix iii: Topic Guide

Appendix i.

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: MRSU-23/24-43526

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

Expectation vs. Fantasy: Exploring Epistemic Value Competence in the Biomedicalization of Psychedelic Assisted Therapy (PAT)

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my dissertation research for a MSc in Global Health, Social Justice and Public Policy. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the project?

The purpose of the project is to contribute to the completion of the Master of Science degree at King's College London of Global Health, Social Justice and Public Policy. It aims to understand how expectations constructed through knowledge systems may impact the trajectory of PAT biomedicalization. The interview will serve to evaluate how the origins of different epistemological perspectives impact the discourse of PAT and examine the impact of cultural perspectives on the acceptance and efficacy of PAT in a clinical trial context. To complete this project, I will search for similar themes of how the relationship of these variables can impact the results of clinical trials and overall patient experience.

Why have I been invited to take part?

You are being invited to participate in this project because of your participation or proximity to conducting research involving outcomes in PAT. This puts you in the inclusion criteria for the study. With your exposure to the epistemological structure used to conduct trials using psychedelic components along with your interaction with participants engaging in the studies, we aim to understand the influence origins of knowledge and prior expectations have on PAT experiences.

What will happen if I take part?

If you choose to take part in the project you will be asked to engage in one semi-structured interview about your experience as a researcher engaging in clinical trials testing outcomes of psychedelic-assisted therapies. The duration of the interview process should be approximately 30 minutes. I will request you to sign a consent form admitting your understanding of this information sheet.

This will take place within the realm of your comfort with the option of using a neutral, King's College London campus location for a face-to-face interview or via online using Microsoft Teams. Through either method, the interview will be audio recorded and transcribed. The audio recording and initial transcription of the interview will be used to editing the interview to verbatim clean. Redacting any personally identifiable answers to ensure anonymity will also occur here. An example of a question you may be asked can be about your educational background or "Can you describe your understanding of the epistemological origins of psychedelics used in clinical trials?". Another example of an interview question may be "In what ways do you interact with the participants prior to and post administration of psychedelics?" If this portion or another aspect of the interview causes discomfort, you have the right to stop the interview at any time for any reason.

As part of participation, you will be asked to provide details of your educational background and your engagement or influence within clinical research involving psychedelic-assisted therapies. It will also ask you to reflect on epistemic origins influencing these studies. This reflection will provoke reporting expectations you personally held prior to conducting the research and any observations you have made on prior expectations of the patients entering the research you have assisted in. This is necessary for the research to understand the gap being explored on how influential expectations of such treatments are. This will provide structure to the analysis portion of the overall assessment. Any significant body language or non-verbal cues may be recorded alongside the transcription and submitted with your consent.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact me if you have any questions that will help you make a decision about taking part. If you decide to take part we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

What are the possible risks of taking part?

There are no foreseen physical or career related risks in taking part in this interview process. If you feel discomfort at any point, please notify me and know you can withdraw from the study if necessary. No outstanding risk-avoiding measures were put in place; however, your comfort remains a priority from the preparation through the engagement of your participation.

What are the possible benefits of taking part?

There are no direct benefits in participating in this study. It will only serve as a reflective exercise for you and myself in our roles, responsibilities, and epistemic value as agents of the psychedelic renaissance.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR).

In preparation to ensure anonymity and confidentiality, the following preparations and protocols were instilled. The interview will be recorded with your consent via the *Otter* iPhone application for an in-person interface. The same application will be utilized for online interviews via connection of the app to Microsoft Teams (recordings of your face is not necessary for the transcribing process). This will then be moved to a secure King's College account OneDrive within 48 hours of the interview. Your data will be retained in this storage location for up to one-week post-interview. Your identity will remain anonymous in the final report by being assigned a randomized letter. All features indicating your identity within the interview transcription will be reviewed and redacted. By the submission deadline of 04/09/2024, this data will be completely deleted from all platforms. This report will be shared with the module convenors in which no third party will obtain access to your information. Due to the minimal risk nature of the report, your identification will remain confidential. To support this claim, a member of King's College London staff will review and evaluate this credibility.

Data Protection Statement

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR). If you would like more information about how your data will be processed in accordance with GDPR please visit the link below:

 $\underline{https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-o}\\ \underline{f-personal-data-in-research}$

What if I change my mind about taking part?

You are free to withdraw at any point of the project, without having to give a reason. Withdrawing from the project will not affect you in any way. You are able to withdraw your data from the project

up until 10/08/2024, after which withdrawal of your data will no longer be possible due to the anonymized nature of the data of all the interviews and their contribution to my assessment for the course. If you choose to withdraw from the project prior to this date, we will not retain the information you have given thus far.

What will happen to the results of the project?

The outcomes will be condensed into an approximate 12,000 word written report explaining the research process and the analysis of the semi-structured interviews. The contents of the interviews and thematic analysis will serve as my dissertation submission in the MSc program Global Health, Social Justice and Public Policy. The data set containing the anonymization of personal information will remain private.

Who should I contact for further information?

If you have any questions or require more information about this project, please contact me using the following contact details:

eMail: K23083147@kcl.ac.uk

What if I have further questions, or if something goes wrong?

If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project you can contact King's College London using the details below for further advice and information:

Dr Filippa Lentzos filippa.lentzos@kcl.ac.uk

OR

Guntars Ermansons

guntars.ermansons@kcl.ac.uk

Thank you for reading this information sheet and for considering taking part in this research. Appendix ii.

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES



Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Expectation vs. Fantasy: Exploring Epistemic Value Competence in the Biomedicalization of Psychedelic Assisted Therapy

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study.

1.	*I confirm that I have read and understood the information sheet dated 19/04/2024 for the above study. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction.	
2.	I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason, up until $04/05/2024$.	
3.	*I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation.	
4.	*I understand that my information may be subject to review by responsible individuals from the College for monitoring and audit purposes.	

Name of Researcher		Date	Signature Signature		
Name of Participant		Date	Signature		
8. I consent to my interview being audio recorded.					
7. I understand that the information I have submitted will be published as a report wish to receive a copy of it.					
6.	6. I agree that the research team may use my data for future research and understand to any such use of identifiable data would be reviewed and approved by a research eth committee. (In such cases, as with this project, data would not be identifiable in any report).				
3.		y me in any research	nonymity will be maintained and it will not be noutputs.		
`	I understand that c	confidentiality and a	nonymity will be maintained and it will not be		

Appendix iii.

Topic Guide

Participants Education and Exposure to Topic

- Can you give me a brief outline of your educational background that led you to the profession you are in today?
- Where did psychedelics start to be integrated into your education?
 - What background of psychedelics have you been exposed to in academic settings?
- Can you describe your understanding of the (epistemological) origins and knowledge foundations of psychedelics used in clinical (setting) trials?
 - o To help: where you're gathering the information, how far back it dates...etc.

Practical Clinical Involvement

- Could you briefly explain the premise of the study/ies you have conducted involving psychedelics?
 - What psychedelic?
 - o Double blind?
 - What were you addressing or identifying in the research question?
- In what ways are you interacting with the participants prior to and post administration?
 - What training and qualifications are required for clinicians conducting PAT research?

Participant Briefing

- To give some insight into what the participants may understand about the experience they may be undergoing, can you give me a brief understanding of the information provided to the participants?
 - Does the background information you provide your participants include where the psychedelic was sourced?
 - From which bodies of knowledge is the background and consent information for participants in PAT derived?
 - Does the information provided to the participants usually provide them with anticipated effects?
 - How far back is the information you use to guide the trials dated?
 - o Can you tell me about the sources of information used to guide the trial?
 - How do these epistemic sources ensure the reliability and comprehensiveness of the information provided to participants?
- Have the exclusion or inclusion criteria of the participants in your study included prior knowledge of or consumption of psychedelics? (Did the recruitment process of the participants in your study include criterion based on their prior exposure to psychedelics?) *Note: the majority of the time this question remained unasked because it was answered via other avenues of conversation.*
 - Do you agree or disagree that excluding patients' prior experiences with mental health treatments (psychedelic application or otherwise) is an example of an epidemic injustice that impacts the outcome of your research?
 - Is there a space for participants to tell you what they know about psychedelics?

Clinical Observations

- What range of demeanors do you observe from the participants prior and post administration?
- Are participants' expectations assessed prior to the start of the therapy?
 - If so, what tools or methods are used to measure these expectations?

- What guidelines can be developed for clinicians to better manage patient expectations?
- Is there effort put into having the expectations of participants be a control variable?

Application to better PAT from Reflection

- Is there support provided to help participants reconcile their expectations with their actual experiences?
 - Do either parties consider or mention religious affiliations when visual or auditory hallucinations are related to this topic?
- Can you provide examples of how cultural perspectives have been integrated (or overlooked) in psychedelic clinical trials?
 - In your experience, how do the findings from clinical trials align or conflict with traditional knowledge about psychedelics? (non-western)
- How can findings about the role of expectations inform clinical practices in PAT?
- Do you think a prior misconception of effects of the administered psychedelic impacts the results?
- Do you have any questions for me?

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