Beckley Psytech

PsyPAN
Psychedelic Participant Advocacy Network

PATIENT IMPACT REPORT

IN THE PARTICIPANTS' WORDS

PATIENT INSIGHTS FROM PSYCHEDELIC CLINICAL TRIALS

AUTHORS
Ian Roullier, Leonie Schneider, Katharine Lazenby, Michael Bourne, Caroline Lilley, Fiona Dunbar, Mathieu Seynaeve and Sophia Lobo

Beckley Psytech

PsyPAN

Psychedelic Participant Advocacy Network

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ABOUT THIS REPORT

This report seeks to share insights collated from four patients with experiences of participating in psychedelic clinical trials with the wider psychedelic research industry. The report aims to amplify the participant perspective and highlight potential options that could improve the experience for future participants.

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INTRODUCTION

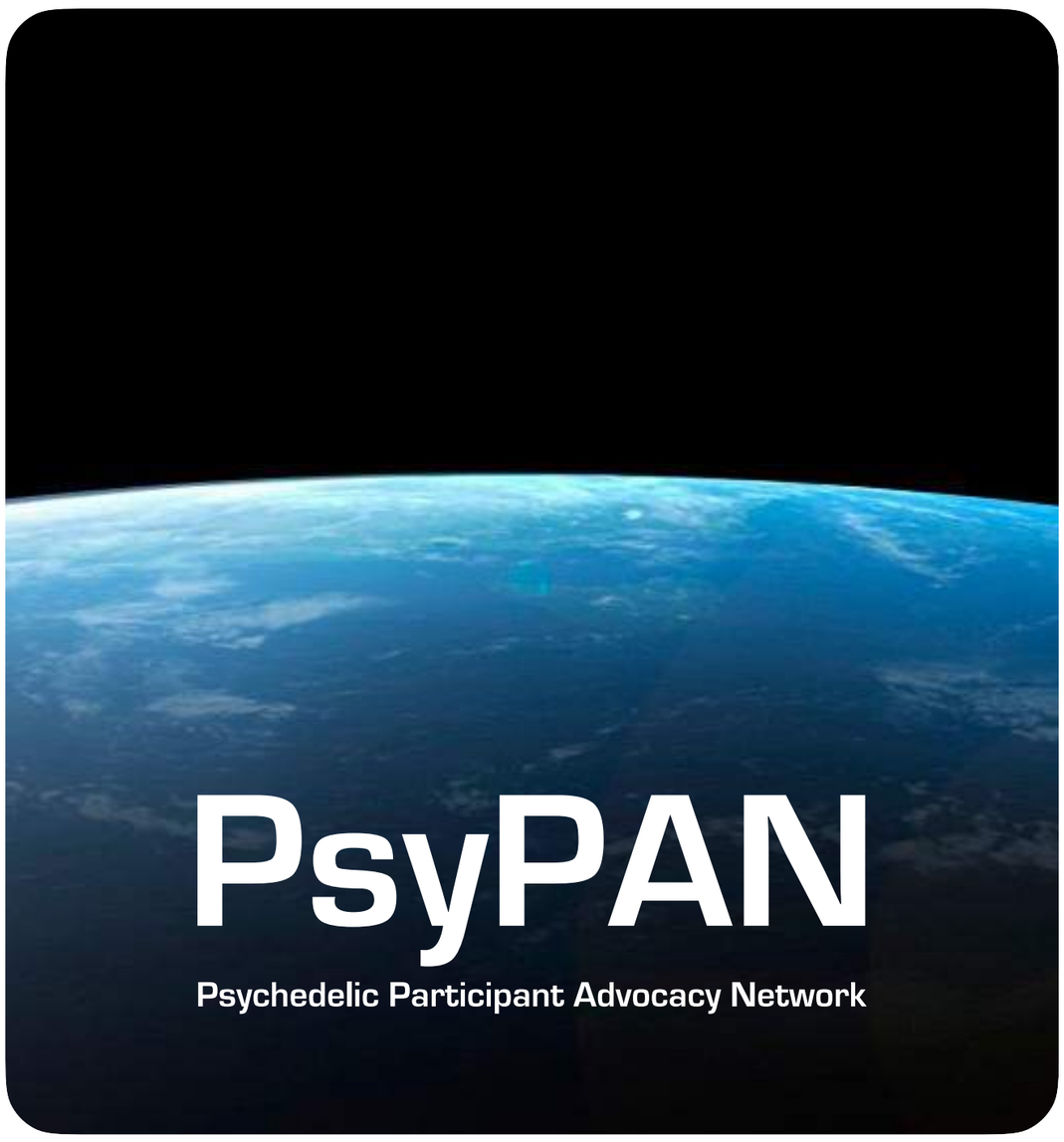
It is estimated that 10% of the global burden of disease is made up of mental, neurological and substance use disorders[1].

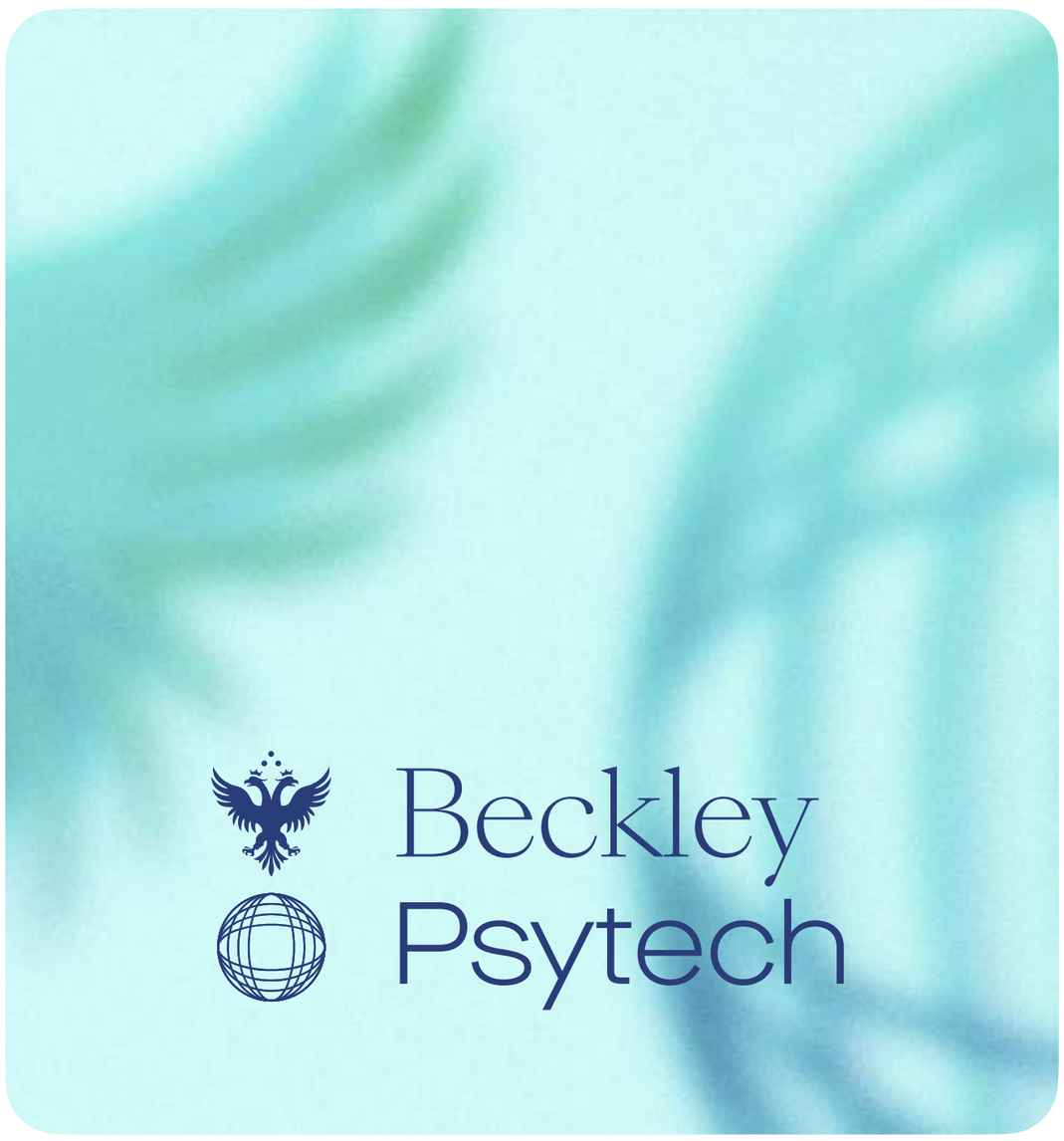
For many of the individuals living with these conditions, current pharmacological treatments can have negative side effects, and inadequate treatment outcomes[2].

However, psychedelic science has been revitalised in the past two decades and early positive signals from modern psychedelic studies have led to a burgeoning R&D space that seeks to research the therapeutic applications of psychedelic compounds to deliver clinically meaningful results for patients in need. As psychedelic R&D continues to work with participants and patient populations, understanding their unique trial experiences is a valuable resource to the research community.

1 · World Health Organization, "Mental Health: Strengthening Our Response," WHO, Published July 8, 2022 (accessed November 21, 2023)
https://www.who.int/news-room/facts-in-pictures/detail/mental-health
2 · The Lancet Commission, "Global mental health and sustainable development 2018 ,https://pubmed.ncbi.nlm.nih.gov/30314863/,PublishedOctober 9,2018 (accessed March 05, 2024)

ABOUT





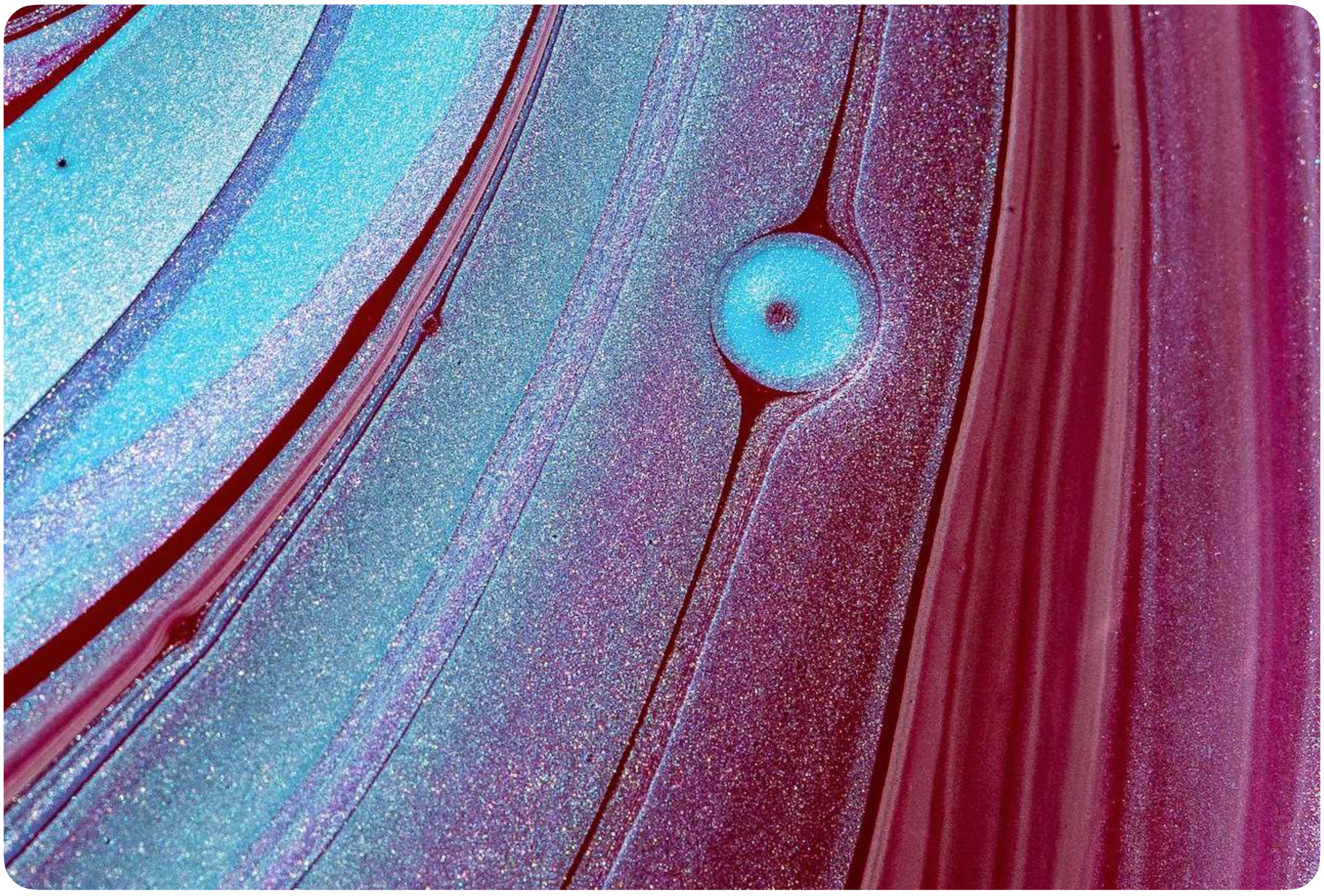
The Psychedelic Participant Advocacy Network (PsyPAN)[3] is a not-for-profit organisation that advocates for, and seeks to improve, the wellbeing of psychedelic clinical trial participants by building a community of 'experts-by-experience' to shape best practices across all levels of the global psychedelic sector. PsyPAN provides opportunities for its members to feed into clinical trials to ensure that the patient's voice is heard and improve the likelihood that trials and treatments have the most beneficial and positive impact on patients.

Beckley Psytech Ltd (BPL)[4] is dedicated to improving the lives of people suffering from neuropsychiatric disorders. As an innovative, mission-driven, clinical-stage biopharmaceutical company, we aim to transform psychedelics into effective and rapid-acting medicines that are supported by rigorous scientific investigations and subject to high-quality clinical trials. We also believe in seeking to understand and add value to all of our stakeholders.

With 'patient focus' as a core company value, BPL is committed to seeking participant-informed insights throughout its R&D process. To this end, BPL and The Psychedelic Participant Advocacy Network (PsyPAN) formed a Patient Council in 2023.

The Patient Council comprised 4 patient experts with personal experience of participating in psychedelic clinical trials, and 3 members of BPL's team with expertise in patient support and developing psychedelic clinical trials. All of the participants had received an active dose of a psychedelic study drug in a UK clinical trial setting.

3 · The Psychedelic Participant Advocacy Network (2023), https://www.psypanglobal.org/
4 · Beckley Psytech (2023), https://www.beckleypsytech.com



APPROACH

Three Patient Council workshops were convened to gather insights into the participants' clinical trial experience. In addition, the patient experts contributed key insights based on the collective experiences of the 70+ PsyPAN members. The three workshops reflected on four key areas:

- Clinical trial recruitment
- Pre-treatment
- Drug dosing
- Post-treatment, trial integration and post-integration

Each workshop was recorded and transcribed to facilitate analysis of participant-generated insights that would help BPL team members identify potential actions that would be supportive of future participants' needs. The final workshop aimed to validate the identified insights and discuss potential support options. The BPL team then developed a report based on these insights and, as a final step, the report was reviewed by all the participants and amended according to their feedback.

REFLECTIONS

The Patient Council workshops revealed a wealth of valuable insights. To maximise their contribution to the research community, it was agreed that the patient expert reflections should focus on observations that were new, specific to psychedelic research and most critical to the participant community.

3 · The Psychedelic Participant Advocacy Network (2023), https://www.psypanglobal.org/
4 · Beckley Psytech (2023), https://www.beckleypsytech.com

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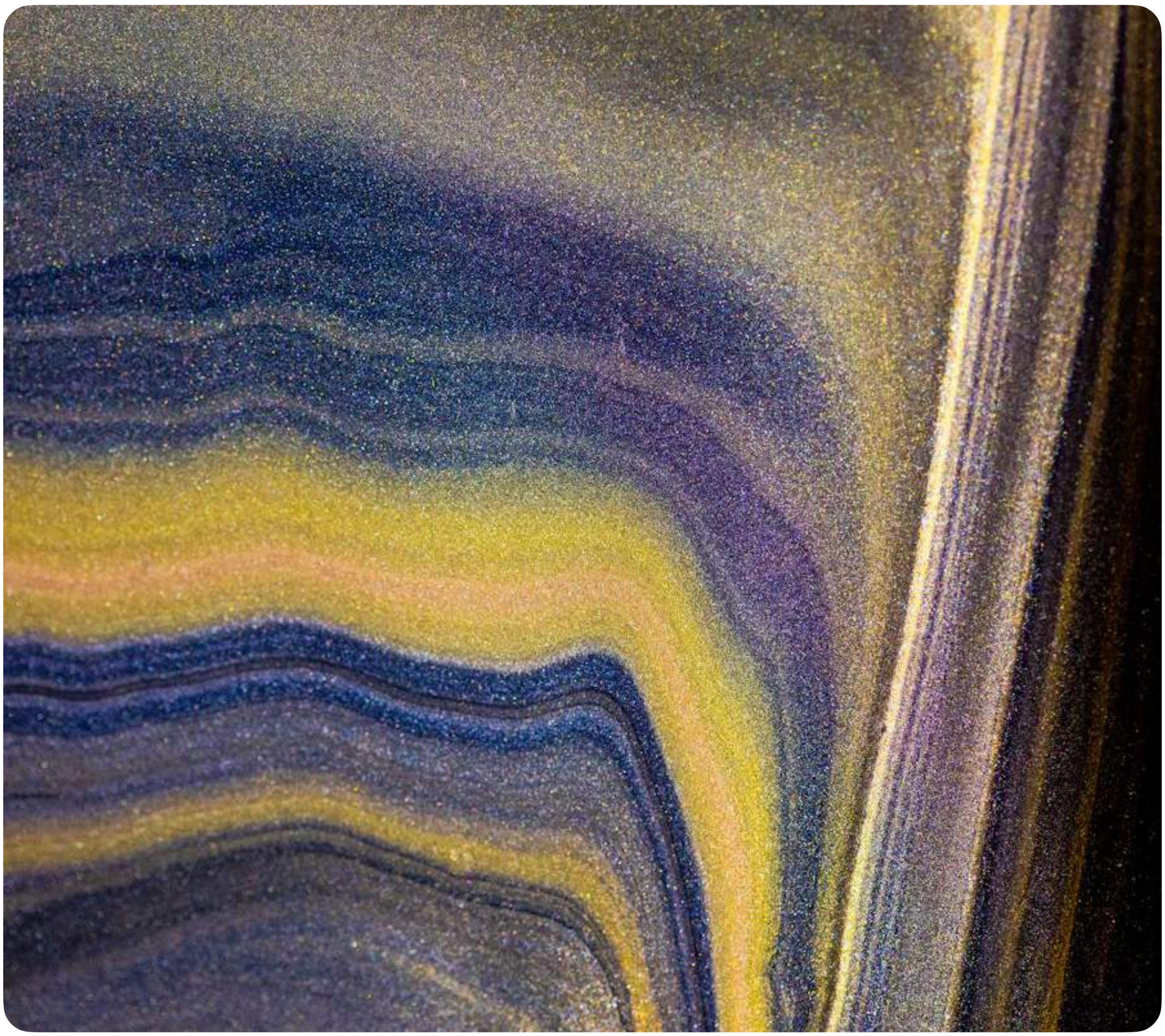


KEY REFLECTIONS AND POTENTIAL OPTIONS

1 CONDUCTING A TRIAL VS ACCESSING A TREATMENT

2 THE UNSEEN PARTICIPANTS

3 THE EXPERIENCE WITH THE RESEARCH SITE EXTENDS BEYOND THE TREATMENT TEAM TO EVERY INTERACTION

4 DUE TO HIGH PUBLIC INTEREST FOLLOWING CLINICAL TRIAL COMPLETION, SOME PARTICIPANTS HAVE FELT COMPELLED TO SHARE THEIR EXPERIENCES PUBLICLY, BUT HAVE HAD NEGATIVE EXPERIENCES DOING SO

5 SOME PARTICIPANTS EXPERIENCE END-OF-TRIAL TERMINATION “GRIEF”

6 SOME PARTICIPANTS SEEK FURTHER SUPPORT AND COMMUNITY FOLLOWING THE TRIAL

1 CONDUCTING A TRIAL VS ACCESSING A TREATMENT

> This trial was sort of a last resort option... You've got to be careful that you're not giving anything away in the recruitment stage and getting hopes up falsely
>
> Participant Quote

> My first trial was open label, which I do think made a massive difference, because you knew you're going to get the help that you desperately hoped for. The second trial was placebo controlled, and there was no open label extension. So that did feel like this is my one shot.
>
> Participant Quote

> For me, the hardest part of the trial is knowing that once a patient knows there's a remedy for their suffering, knowing that the remedy is not available any more can be soul destroying.
>
> Participant Quote

REFLECTION

The FDA defines clinical trials as a means “to determine whether a new drug or device is safe and effective for people to use”[5]. For the participants, taking part in psychedelic clinical trials represented an opportunity to receive a potentially transformative treatment for their mental health condition. For some, these trials were seen as a last resort. The participants cited media sources and the large amount of “real-world evidence” as drivers of this expectation. Given the context of the perceived quantity of “real-world evidence” specific to psychedelic research, it is important to recognise this nuanced yet important divergence in stakeholder perspectives.

Patients are seeking improvement to their symptoms while pharmaceutical companies aim to develop treatments that are safe and effective, working within the constraints of regulatory guidelines and study design to protect the integrity of the data and scientific and statistical validity. Clinical trials need to be conducted in a way that seeks to minimise bias and prioritise participant safety, whereas the participants acknowledge their focus is on access to a potential treatment. Acknowledging that this is not always possible, PsyPAN advocates for clinical trial design of psychedelics that allow all patients to receive an active dose, and if patients respond, access to further treatment as clinically indicated should be made available.

POTENTIAL OPTIONS DISCUSSED

To reduce this tension, clinical trial teams and sponsors could inform participants of the rationale and reasons for aspects of trial design that participants may perceive as lacking patient focus. Participants acknowledged they would benefit from being thoroughly prepared for a potential allocation to a placebo group (if in the protocol), the potential for non-response or any other unforeseen challenges that may be at odds with the participant's motivations, as well as the time required to complete the assessments and feedback process.

5 · US Food and Drug Administration. Accessed at: https://www.fda.gov/patients/clinical-trials-what-patients-need-know/basics-about-clinical-trials

2 THE UNSEEN PARTICIPANTS

> “
>
> I think, especially if your support system is psychedelic naive, you come out having had this insane experience, which is life changing and people don't know how to respond to you, your own people, your family.
>
> Participant Quote

> “
>
> I think I had a session with the study team and my support system to talk about what my support needs might be. So that was a really key element and actually, in my experience, was enormously beneficial.
>
> Participant Quote

REFLECTION

Members of the participants' support network played a critical and potentially under-recognised role in participants’ experiences. The workshops identified that the perception of psychedelics from the participant's support network resulted in them either encouraging or discouraging participation. Three participants felt it was their responsibility to educate and inform their support network throughout the process, and the participants acknowledged this as a burden. This was not the case for one participant, as support and information were provided to their support network as part of the clinical trial they took part in.

POTENTIAL OPTIONS DISCUSSED

Providing resources for the participant’s support network may help create a supportive environment around the clinical trial process and contribute to a better overall experience for the participant. For example, a support booklet could include an overview of the clinical trial process and procedures, digestible educational material on the study drug under investigation, and information on the emotional and practical burdens associated with psychedelic clinical trials.

3 THE EXPERIENCE WITH THE RESEARCH SITE EXTENDS BEYOND THE TREATMENT TEAM TO EVERY INTERACTION

“

The creation of trust begins with the first contact with potential participants. I ended up going to some pretty dark and difficult places. And my belief is that I only did that because I felt safe enough to because of the relationship that started 6-7 months prior to actually having the doses.

Participant Quote

“

I think when things start dropping, it does end up falling on the patient.... They (treatment administration team) were phoning me at 9pm with paperwork and follow ups... it was just chaotic.

Participant Quote

REFLECTION

The “set and setting” principles of psychedelics research are recognised as an essential consideration within psychedelic clinical trials. Though “setting” can be largely controlled within a clinical trial site, creating or promoting a 'set' conducive to therapeutic changes requires careful consideration.

The workshops highlighted that trust was an essential interpersonal feature between the participants and the research team. Participants considered every interaction with the clinical trial team—from administrative recruitment emails to support during treatment—as critical elements of trust building.

POTENTIAL OPTIONS DISCUSSED

Training the research team in compassionate participant communication could facilitate the establishment of trust. Elements include engaging in behaviour and language that promotes trust from the start of recruitment and is continuously built upon throughout the clinical trial process. Incorporating culturally appropriate tools, language, and behaviours could also support participant interactions.

Compassionate participant communication also includes the research team who could seek to ensure an organised and smooth clinical trial experience for the participant, enabling the participant to feel confident in the research team to support them throughout the clinical trial process.

4 DUE TO HIGH PUBLIC INTEREST FOLLOWING CLINICAL TRIAL COMPLETION, SOME PARTICIPANTS HAVE FELT COMPELLED TO SHARE THEIR EXPERIENCES PUBLICLY, BUT HAVE HAD NEGATIVE EXPERIENCES DOING SO

> “
>
> Psychedelic experiences are ineffable, trying to describe the experience with words, is like trying to describe your favourite piece of music with lego. You end up feeling like you’re either trying to find the most creative language to emphasise the unique and often spiritual experience, that ultimately sounds “crazy” to those who haven’t experienced.
>
> Participant Quote

> “
>
> I think there is a process of educating the media on these medicines and how to deal with participants coming out of these trials or treatment centres as it becomes mainstream. Stigma still exists, so preparing patients to know reactions might differ. And, you know, making the participant understand it's not about them, it's about that person's reaction to their response.
>
> Participant Quote

REFLECTION

Intensified by the stigma that can accompany both psychedelics and mental health, the participants explained the significant emotional toll of reliving the psychedelic experience publicly. In some instances, this sharing was met with dismissive, minimising and negative reactions. The participants believe speaking publicly can/ should be empowering, but support is needed before and afterwards to ensure this.

POTENTIAL OPTIONS DISCUSSED

The participants now advise other participants to protect their emotional well-being by only sharing their experiences publicly when they feel they are psychologically strong enough to do so following the clinical trial data publication. PsyPAN currently provides direct peer support before and after media interviews. Furthermore, PsyPAN plans to create media and industry guardrails and guidelines around the appropriate interaction with participants following the psychedelic clinical trial experience to help safeguard participants by educating stakeholders on how best to communicate with participants.

5 SOME PARTICIPANTS EXPERIENCE END-OF-TRIAL TERMINATION “GRIEF”

“

Having had access to such a transformative, powerful and ineffably cathartic form of 'treatment' or 'medicine'. The grief was not only related to the loss of relationships to the therapist/guides/trial team but the ending of an incredibly intense experience. The experience was one of the most important in my entire life.

Participant Quote

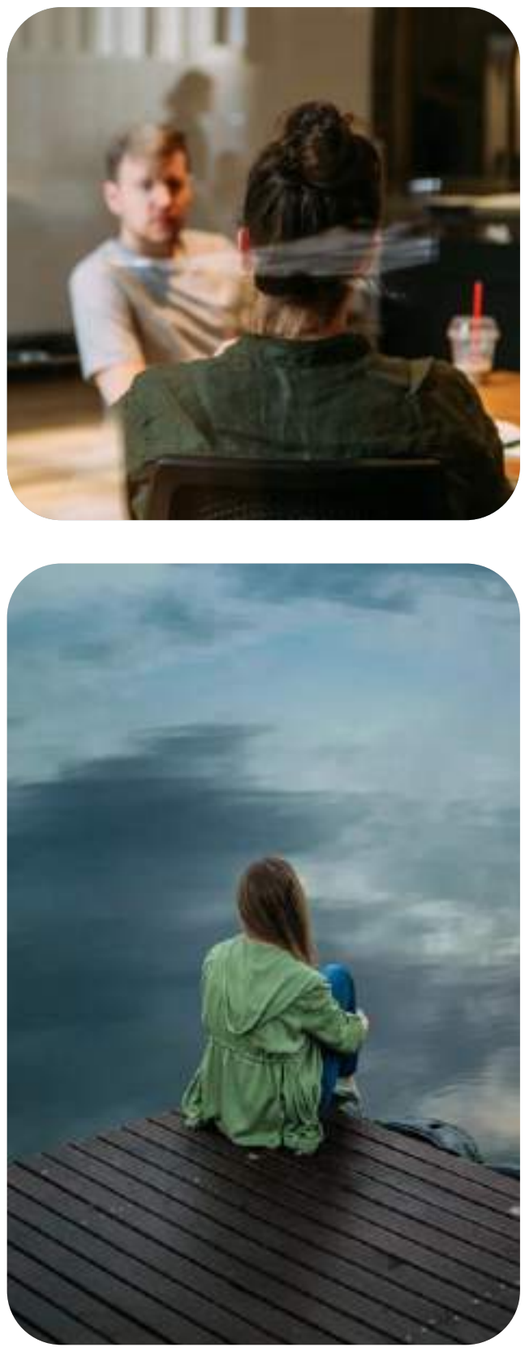
“

I felt a lot of grief at my trial ending because I trusted my healthcare professionals so much, I felt very connected to them like they had accompanied me in the rawest expression of my emotion, a kind of expression that I don't think anyone in my life has ever seen. They had witnessed aspects of myself that I just don't let that other people see. And so the trial coming to an end was quite a painful thing for me.

Participant Quote

REFLECTION

Three participants experienced feelings of grief when their clinical trial experience came to an end. The participants felt this was due to the strong relationships they had built with the research team, which were actively nurtured to support the participants through the study. One participant did not feel a sense of grief, they believe this may have been due to their research team clearly articulating the finite nature of the relationship and their encouragement to cultivate participant ownership over their own “healing journey”.



POTENTIAL OPTIONS DISCUSSED

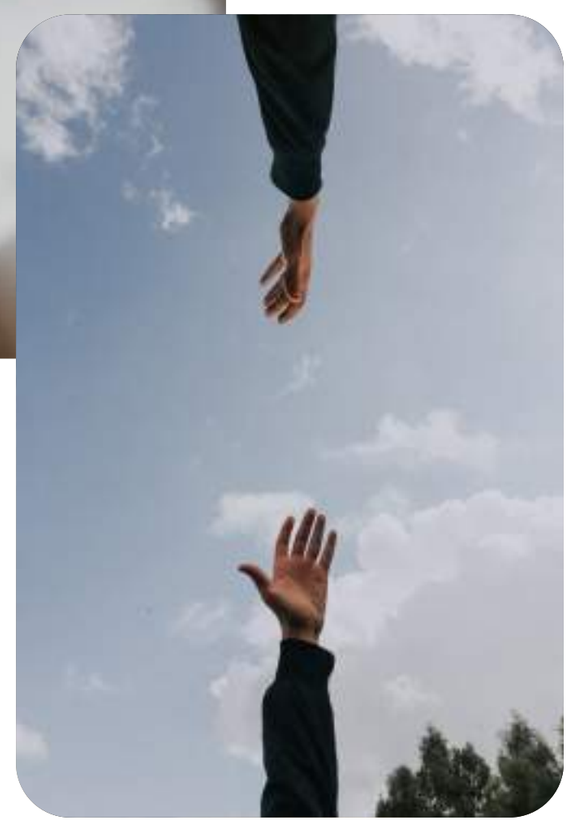
Preparing participants for the temporary nature of the relationship between the research team and the participants could be discussed at the beginning of the clinical trial. This may help mitigate some of the grief experienced at the end of the trial process and empower the participant to continue their own path after the clinical trial. The balance for research teams is to seek to do this in a way that does not minimise the potential depth and importance of that relationship for the participants during the trial experience. Here the participants agreed that signposting to supportive communities at the end of the trial could diminish the feelings of grief. Those responsible for trial design and seeking ethics approval could aim to connect with relevant peer support groups where available and if agreed, submit the group's information or leaflets as part of the trial ethics approval. This would enable researchers to signpost participants to appropriate groups at trial termination.

6 SOME PARTICIPANTS SEEK FURTHER SUPPORT AND COMMUNITY FOLLOWING THE TRIAL

> “
>
> There is a value in spaces for psychedelic clinical trial participants to validate experiences. It is such an extraordinary and extreme experience if you are left alone to manage these experiences... that's poor care.
>
> Participant Quote

REFLECTION

The participants explained that the fear of stigma (described above) as well as the desire to continue to process and understand the experience led participants to describe feelings of isolation and a desire to seek community following their participation in psychedelic clinical trials. Given the uniqueness of the psychedelic experience within a clinical trial ecosystem, the participants described a desire to connect with other people who had shared in this experience and could mutually support one another. All participants acknowledged that if the treatments were available, they would seek to continue accessing therapeutic support. As this is not currently possible, the participants recognised that supporting each other in formalised support groups (if made available) could be helpful.



POTENTIAL OPTIONS DISCUSSED

Peer support groups may serve as a feasible solution to meet participant support needs after the trial is terminated. A Peer-Support Program may minimise emotional isolation following the psychedelic clinical trial and support participants to integrate their experiences through community and the sharing of personal experiences.

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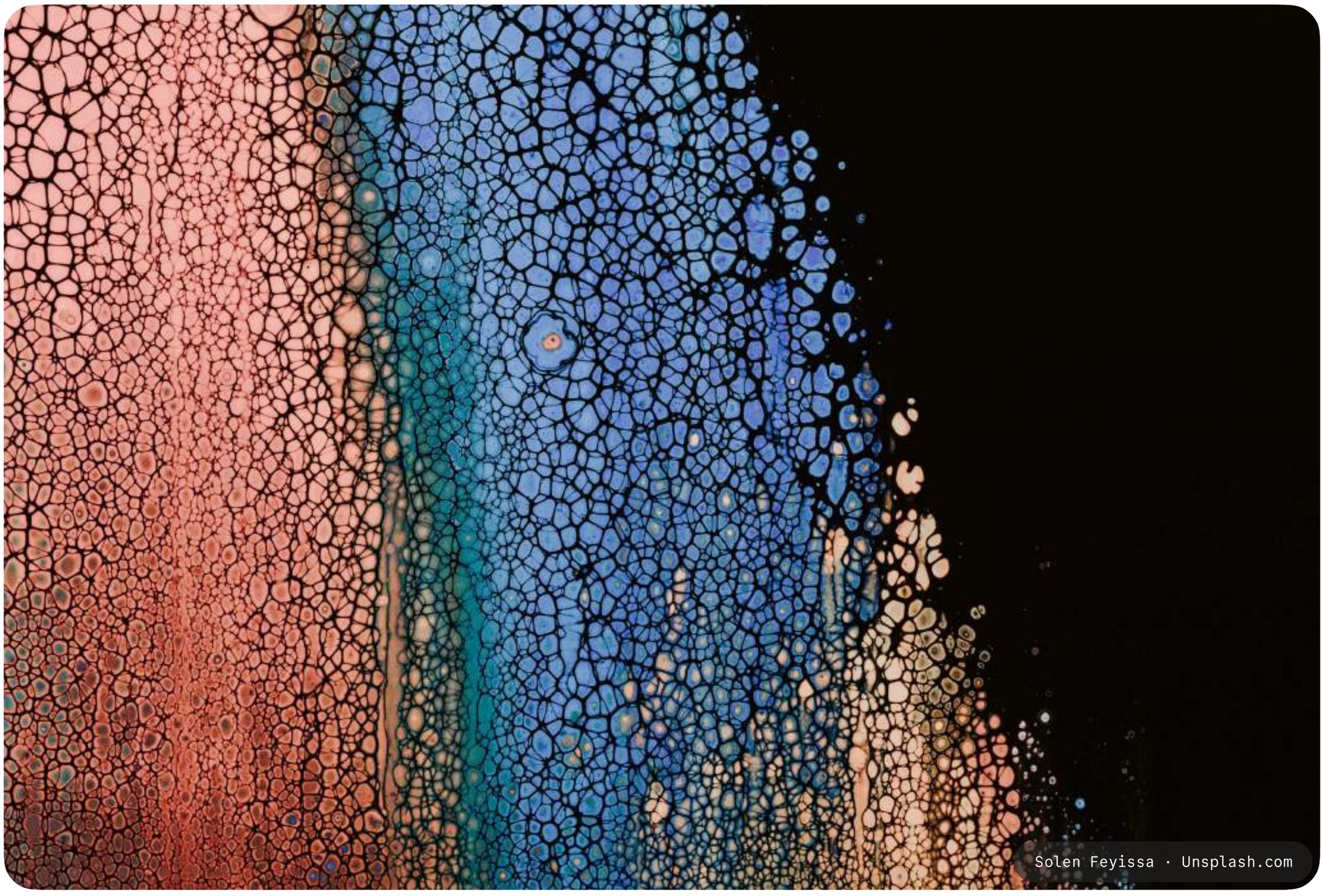

CONCLUSION

This report sought to identify new participant insights relevant to psychedelic research. It is important not to underestimate the vast and life-changing impact the psychedelic trials had on the four participants who took part, however, every participant had unique and different experiences and this will be true of all participants undertaking a psychedelic trial. This highlights how critical seeking to eliminate bias in every participant interaction is, to protect the participants from unfulfilled expectations. The participants look forward to a future where their feedback and perspectives directly impact future participants' clinical trial support and where feasible, peer support is available to participants post-trials.

We acknowledge the inherent limitations of this report, such as sample size constraints and biases due to all participants receiving an active study drug. Future research should prioritise participants with more varied trial experiences and explicitly explore factors such as race, ethnicity, gender identity, sexual orientation, disability and socioeconomic status to better understand the nuanced experiences of recognised marginalised communities within psychedelic clinical trials. Additionally, incorporating an intersectional lens and engaging with diverse stakeholders will foster greater inclusivity and equity in psychedelic research. The latter though is dependent on ensuring inclusive and diverse recruitment into psychedelic clinical trials.

3 · The Psychedelic Participant Advocacy Network (2023), https://www.psypanglobal.org/
4 · Beckley Psytech (2023), https://www.beckleypsytech.com

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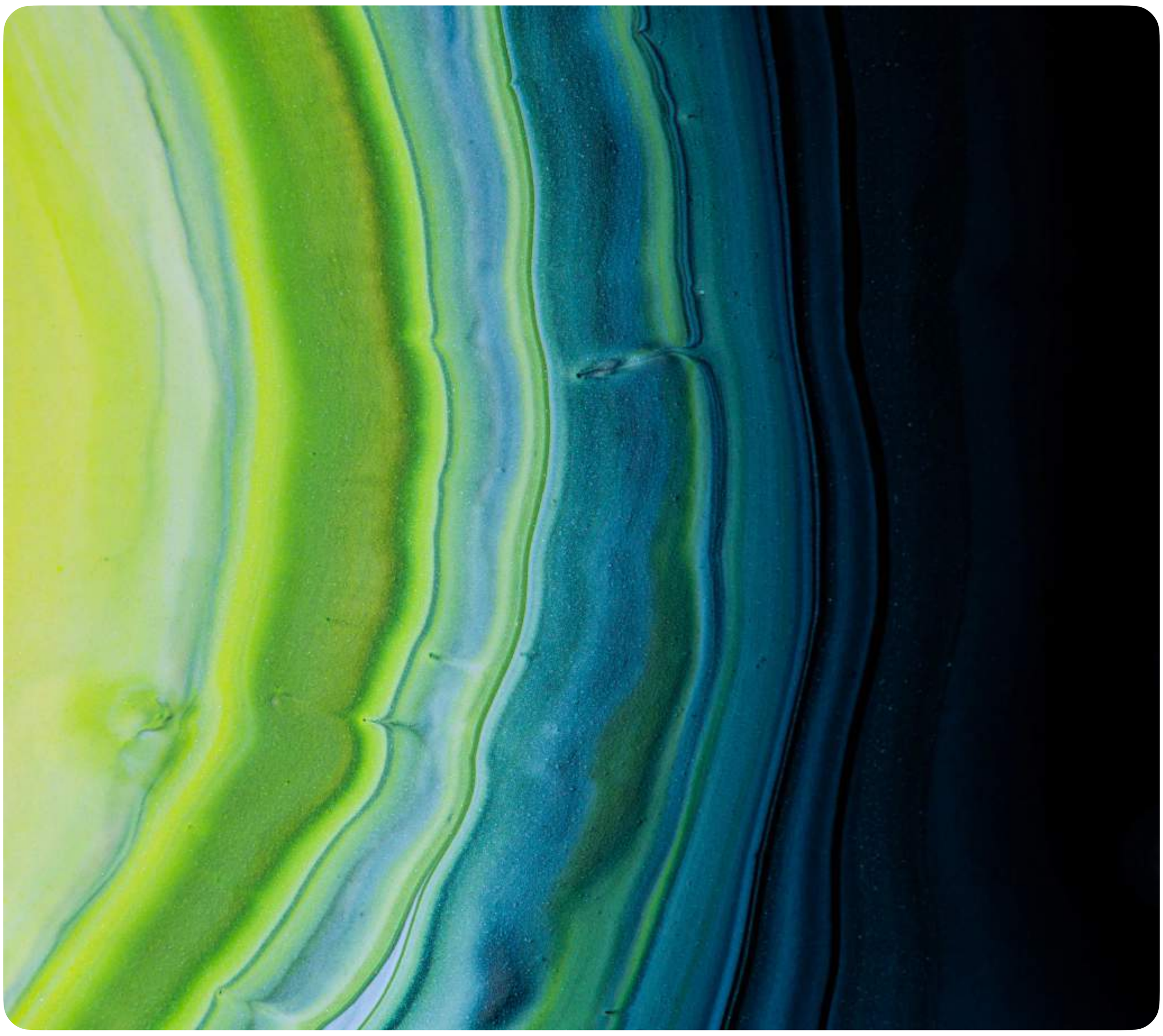

BECKLEY PSYTECH COMMITMENT

Through this collaboration with PsyPAN, BPL has gained invaluable insight into participants' experiences within psychedelic clinical trials, all of which serve to evolve our current trial support. We recognised the need to identify ways to support the participant community following trials and have provided PsyPAN with funding for a feasibility assessment of a post-trial peer support model. As a result of the feasibility study, we were proud to fund an unrestricted grant to PsyPAN to initiate an industry-wide post-participant peer support pilot program. The 12-month pilot is currently available to 20 UK-based participants who have taken part in a psychedelic-based clinical trial for a serious mental health illness. PsyPAN will facilitate monthly virtual sessions and trained co-facilitators will lead each session, starting with a meditation and grounding exercise. To provide some structure, a loose topic will be presented at the beginning of each meeting for inspiration and reflection.

The participants will be asked to consider the impact of the peer support program and PsyPAN plan to publish these findings following the end of the pilot. Should the pilot program be successful and PsyPAN receive adequate funding, PsyPAN is keen to expand the program to more countries in order to contribute to a scalable peer support ecosystem.

ACKNOWLEDGEMENTS

Thank you to the participants who bravely and openly shared their lived experiences with us in order to amplify the participant’s voices in psychedelic clinical research. Thank you also to Beckley Psytech team members for sharing their insight and expertise.

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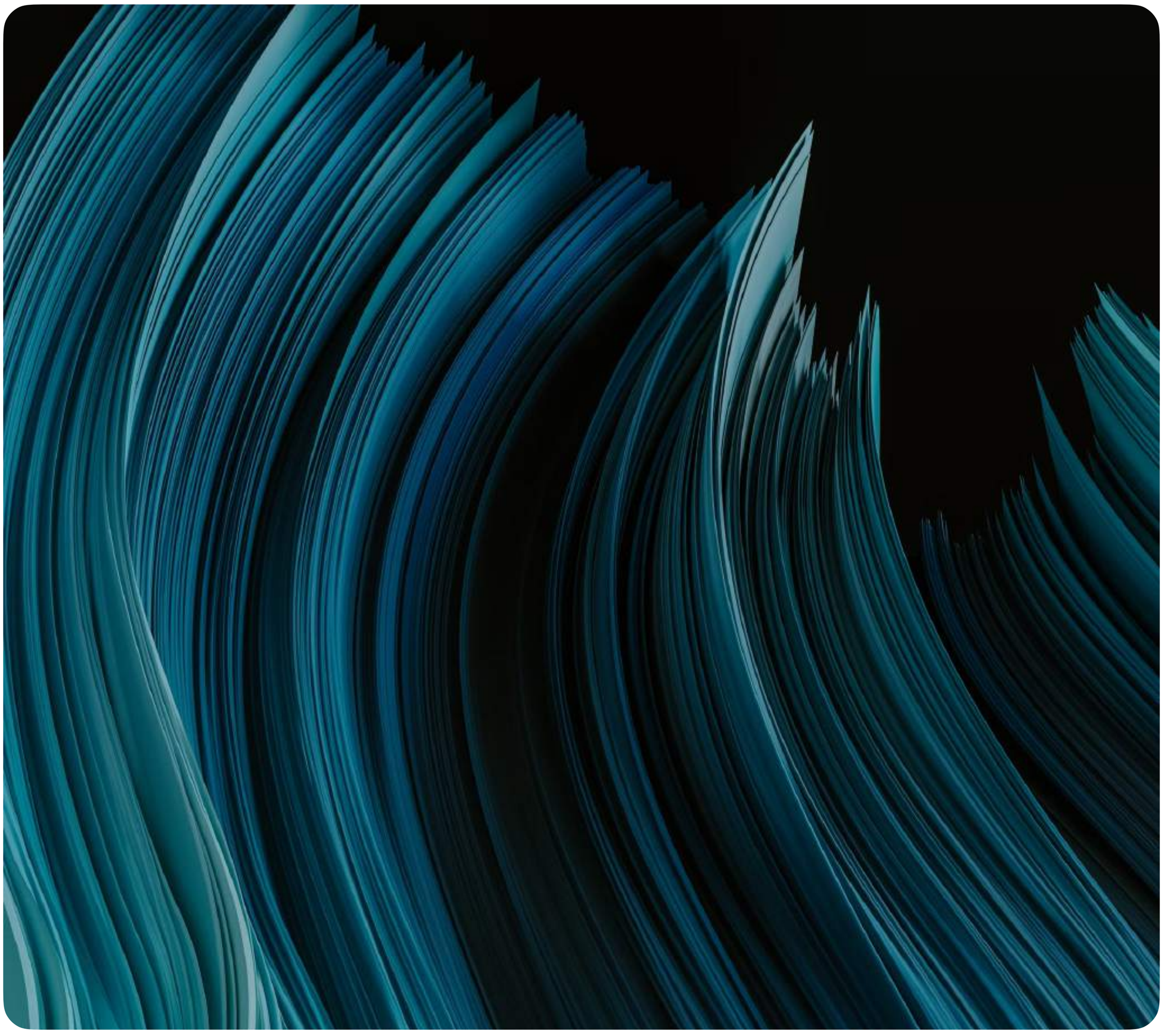

ABOUT THE PARTICIPANTS

IAN ROULLIER

Ian is the co-founder of the Psychedelic Participant Advocacy Network (PsyPAN) and an expert by experience, having taken part in two clinical trials examining the effect of psilocybin on treatment-resistant depression at Imperial College (2015) and King's College (2019). He has spoken at the European Parliament, European Medicines Agency and at various events and conferences. Ian is also an ACER Integration sharing circle facilitator and a participant representative for the King's College PsiDeR trial steering group. He co-founded PsyPAN with Leonie Schneider in 2021 to help amplify and represent participant voices, help safeguard future participants receiving psychedelic-assisted therapy and establish peer support spaces post-treatment.

LEONIE SCHNEIDER

Leonie is a passionate mental health advocate, committed to expanding access to psychedelic assisted therapies by advocating for the safe and integrated use of psychedelics. After participating in a Psilocybin for Depression trial at Imperial College (2019) and Small Pharma's DMT for Depression trial (2022), she co-founded the Psychedelic Participant Advocacy Network (PsyPAN) with Ian Roullier to help inform the delivery of trial and treatment design from a participant perspective.

Leonie has spoken extensively on national and international platforms including the BBC, ICPR and the upcoming Psychedelic Chronicles documentary. She is also a circle facilitator for the ACER Integration Community and is training in transpersonal psychotherapy.

Leonie's recognition as one of the top 20 influential, innovative, and disruptive Women in Psychedelics speaks to her commitment to enhancing participant well-being and improved outcomes for all who access these treatments.

MICHAEL BOURNE

Michael's journey into psychedelics began with participation in the ground-breaking 2015 Imperial College clinical trial exploring psychedelics for depression. Since then, Michael has become a vocal advocate for the therapeutic potential of psychedelics, sharing experiences and insights at various conferences and in clinical research scenarios. Michael is a member of the steering committee for the Psychedelics for Depression (PsiDeR) trial, based at King's College London and works with PsyPAN, the Psychedelic Participant Advocacy Network. Michael is deeply intrigued by the intersection of music and psychedelics, experimenting with musical tracks that explore the profound ways in which music and sound design can shape the psychedelic experience.

KATHARINE LAZENBY

Katharine is an expert by experience, drawing on her lived experience of mental illness, psychiatric care and inpatient hospitalisation in a variety of roles. Based in London, she has worked for an NHS mental health trust for the last six years and is also a trustee for two mental health charities. Katharine also delivers mental health training to health and social care staff across North East London, is a visiting scholar at London Southbank University and has spoken at a number of conferences. She is particularly passionate about the impact treatment settings, especially ward environments, can have on patient wellbeing and the power of art and creativity in nurturing recovery. Katharine took part in a psychedelic clinical trial in 2022, and has become a committed advocate for research into the potential of psychedelics in the treatment of mental illnesses and recovery support.

WORKING WITH PATIENTS IN MIND

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