

AKADÉMIAI KIADÓ

Real-world evidence of the collective effects of psychedelic therapy: Evaluating from the grassroots

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ABSTRACT

With a surge in critiques levelled against the evidence generated by randomised controlled trials in the study of psychedelic-assisted therapy (PAT), and the legalization of PAT in select jurisdictions such as Australia, and Oregon and Colorado in the United States, we consider what form the real-world evidence of its effects could take. Specifically, we propose to complement individual-level data-gathering (the usual remit of pharmacovigilance procedures) with evidence of PAT's collective effects. Taking our cue from long-standing claims that psychedelics are agents of social transformation, we draw upon the 'transformative paradigm' of evaluation, an approach that is itself oriented around social justice and change vis-à-vis marginalised expertise – or what we approach as 'the grassroots'. To illustrate the potential of such grassroots evaluations, we offer eight examples of social issues that have been discussed in relation to PAT and psychedelics use and, for each, discuss the kinds of expertise that could be brought into the evaluation team and the kinds of questions that could be asked. We further describe our grassroots approach according to three values inspired by the qualities of grass roots themselves: *rhizomatic accountability*, *dark reflexivity*, and *more-than-human hosting*. We argue that these values align with the contemporary experience, practice, and context of PAT. We hope to generate discussion, innovation, and – ultimately – action toward specific study designs that are adequate to the task of documenting, and working with, the transformative potential of psychedelics in contemporary medicalized societies.

KEYWORDS

psychedelics, psychedelic-assisted therapy, social transformation, real-world evidence, transformative evaluation, grassroots, accountability

INTRODUCTION: PHARMACOVIGILANCE BEYOND THE INDIVIDUAL LEVEL?

In December 2023 the Multidisciplinary Association for Psychedelic Studies submitted a new drug application to the Food & Drug Administration for the use of MDMA in the treatment of post-traumatic stress disorder. This landmark submission indexes a new phase in the medicalization of psychedelic substances. At the same time, there has been political desire and legislative movement to make psychedelic-assisted therapy (PAT) available in certain jurisdictions, including Australia, and Oregon, Colorado, and other states in the US. Even in cases where political and legislative changes are not intended to promote the use of psychedelics for therapeutic purposes, in practice there is appetite for using psychedelics in this way, and no way of preventing people from using psychedelics in non-therapeutic contexts with therapeutic intentions in mind.

Unsurprisingly then, given these combined processes of medicalization, decriminalization, and legalization, there has been a growing call for real-world evidence (RWE) in relation

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to psychedelics use generally, and PAT more specifically (e.g., Carhart-Harris, 2022), bringing together the need for the investigation in a post-market approval context of the provision of psychedelics as medications, and public health research into the effects of the availability of psychedelics in legalized and decriminalized jurisdictions.

Any shift in focus of drug researchers and regulators from the randomized controlled trials (RCTs) that are the cornerstone of evidence in a pre-market approval moment, to RWE adequate to the post-market approval context, opens up distinct questions and challenges. The term RWE itself is rhetorically compelling – what legal scholar Daniel Aaron has dryly dubbed a “God term...a phrase that seems so immediately good as to inspire loyalty” (Aaron, 2023: 33). However it usually lacks specificity, for instance when defined negatively as evidence based on any data other than RCT data (ibid.), despite how in practice the real-world data (RWD) used to generate RWE tend to be limited to measures of harm to individuals, documented in electronic healthcare records, hospital room visit reports, spontaneous reports of adverse effects, data on drug misuse, and so forth.

Such measures comprise systems of pharmacovigilance set up to monitor drug effects in the wake of the thalidomide crisis in the 1960s. These systems have evolved over time in response to shifting epistemic priorities. Originally only doctors, dentists and coroners were qualified to report on the adverse effects of drugs, in the 1990s this was extended to pharmacists, and in today’s pharmacovigilance literature there are calls for the admissibility of “patient-reported” and even “patient-generated” outcomes (Barnes, 2022; see also Herxheimer, Comburg, & Alves, 2010). The debates underpinning these shifts have pitted the value of *transparency* (also apparent in the public availability of what are called “spontaneous reporting” datasets) against the need for data that is tractable enough to afford effective signal detection, and have therein been mediated by debates over advances in statistical analyses. As regulators expand the range of acceptable forms of evidence to consider real-world evidence from patient repositories and even social media sources, tensions between ‘anecdote’ and ‘evidence’ continue to play out in new ways (see for example, Lentacker, 2024). Across all these shifts, systems of pharmacovigilance have lacked the political will, funding, and enforcement to be effective (Healy, 2021; Healy & Mangin, 2019).

Any evaluation of PAT in a real-world context would benefit from framing PAT as a) a ‘complex intervention’, administered within b) a wider system with which it is in dynamic interplay. Considering PAT as a complex intervention acknowledges that it has multiple interacting components: for instance, preparation, psychedelic-assisted sessions, and integration sessions, evolving expectations and hope around the treatment outcome for both patients and their wider networks, and new and changed relationships of trust produced through psychedelic experiences. For complex interventions being evaluated in a real-world context, Skivington and colleagues explain,

“A trade-off exists between precise unbiased answers to narrow questions and more uncertain answers to broader, more complex questions; researchers should answer the questions that are most useful...rather than those that can be answered with greater certainty” (Skivington et al., 2021: 1).

The point is not to eliminate uncertainty but to tolerate different degrees of it, across the evidence generated and in proportion to how useful it is to answer the questions being posed. Meanwhile the idea that PAT is in dynamic interplay with a wider system evokes the role accorded to what Betty Eisner called the “matrix” in understanding PAT’s transformative effects (Eisner, 1997). Here,

“...attention is given not only to the design of the intervention itself but also to the conditions needed to realise its mechanisms of change and/or the resources required to support intervention reach and impact in real world implementation” (Skivington et al., 2021: 2).

RWE generated through the evaluation of PAT can inform future RCT designs, for instance in conducting an RCT with a specific sub-population that is discovered through pharmacovigilance systems to be having a higher rate of adverse experiences, or comparing data from trials conducted at time intervals several years apart to test large-scale cultural changes in expectancy, or explore the impact upon participant testimonies of different dominant narratives of how PAT works.

If we add to these attributes of the real-world delivery of PAT, the likely porosity of PAT and non-PAT psychedelic use, and the flows of peoples and practices across boundaries between legal and non-legal jurisdictions of use, we might assume that legally-administered PAT will be a boon to non-PAT psychedelic use. To the extent that this can be tracked, any increase in non-PAT psychedelic use would provide indirect potential pathways, analogous to dark loops in clinical trials (Noorani, Bedi, & Muthukumaraswamy, 2023), for documenting the effects of PAT.

What is curious to us about RWE, RWD, and pharmacovigilance systems in the context of psychedelics, is that the discourse surrounding psychedelic experiences commonly evokes transformation at cultural and societal levels (for instance, Plesa & Petranker, 2023; Brennan, 2020; Bache, Versluis, & Shipley, 2019). This discourse includes emphasis of the non-pharmacological aspects of PAT, the centrality of context, and the layered histories of PAT that haunt the revival of the science and therapeutics with the prospects of fomenting social and political action (Giffort, 2020). In what follows, we elaborate upon this thesis, to demonstrate how the normalization of psychedelics and the medical approval of PAT within systems of mental healthcare heralds an opportunity to expand and reimagine our understanding of what counts as RWE of the effects of these substances *in situ*. What new forms of shared capacitation, social and cultural transformation, and collective safety, risk and harm, are being created? And what ways of knowing PAT are appropriate to these transformative possibilities? Answering these questions takes us well beyond RCTs and standard pharmacovigilance metrics.



EVALUATING PAT'S COLLECTIVE EFFECTS: DRAWING ON A TRANSFORMATIVE PARADIGM

One orientation to collective change is offered by the community psychologist Isaac Prilleltensky, who charts a 3-way distinction between processes of co-optation, amelioration, and transformation in mental healthcare (Prilleltensky, 2014). Prilleltensky describes three forms that *co-optation* can take. First, “adopting methods without the social critique” (ibid.: 152). With respect to PAT, this might be illustrated by defanged forms of social inclusion that welcome the affirming voices of PAT patient advocates without also inviting in their critiques of PAT medicalization. Second, Prilleltensky continues, “changing the system only minimally to silence dissent while maintaining fundamental inequities intact” (ibid.). We suggest this would be at stake for example if, once approved, only members of the most powerful professions can conduct PAT – as seen in the responses to the FDA’s 2023 draft guidance for clinical investigations – or if PAT remains prohibitively expensive for less economically wealthy or privileged populations. Finally, Prilleltensky writes of co-optation as occurring when interventions “change the language without changing the system” (ibid.). This would include using the idioms of empowerment, cultural competence, or decolonisation as mere branding.

With regard to *amelioration*, Prilleltensky describes this as happening when an intervention improves the mental health of individuals without improving the wider “unjust social conditions that led to the [individuals’] problems in the first place” (ibid.: 153). This is the standard individualistic conception of PAT – and the evidence for PAT gathered to date is overwhelmingly gathered with amelioration as its goal (see also Davies, Pace, & Devenot, 2023). By contrast, *transformation* concerns itself with changing the mental health and wider social systems more broadly in line with social justice goals, thereby reducing the need for interventions in the first place (ibid.: 153). This is a vision of mental healthcare that acknowledges the wider institutional, corporate and structural drivers of mental health difficulties, and effectively aspires to render itself redundant through the very interventions it provides.

With Prilleltensky’s definition of transformation in mind, we turn to the development of the ‘transformative paradigm’ within the evaluation field. Twenty-five years ago, the then-President of the American Evaluation Association, Donna Mertens, called for a paradigm shift within evaluations towards the goal of transformation (Mertens, 1999). Responding to the dominance of positivism within US approaches to evaluations and its tendency to inadvertently prioritize and naturalize the experiences, values, and desires of the powerful, thereby reinforcing an unjust status quo, Mertens called instead for a field that explicitly and actively contributes to social transformation. Perhaps most defining, Mertens argued for an approach that is driven by the experiences, values, and desires of those marginalized within the status quo, understanding this expertise as producing the most valid knowledge about how unjust social systems

perpetuate themselves and therefore how to transform them. (Indeed in her own early development of the paradigm, she drew on the expertise of Deaf communities, feminist theorists and Indigenous evaluators to make her arguments and ideas; Cram & Mertens, 2016; Mertens, 2008).

GRASSROOTS EVALUATIONS: SOME EXAMPLE DIRECTIONS FOR PAT

Over the past ten years in the US, UK and Aotearoa New Zealand, we have undertaken, taught and supervised a range of clinical- and community-based evaluations in psychology using the transformative paradigm. In doing so, we partnered with activists within (in particular) mad and racial justice movements, including within parts of the broad psychedelic ecosystem itself. We consider these movements as the ‘grassroots’ – a lively underground of struggles with which our evaluation partners are entangled, and within which there is a constant transfer of resources, knowledge, and energy. Our partnerships enabled us to dig deeper and messier into the transformative paradigm, leading us to believe that *grassroots evaluations* – that is, evaluations that aspire to collective transformation by digging into (in this case) PAT’s entanglement with social movements – offer a way forward for collecting and analysing RWE of PAT in a post-approval landscape.

This section considers the kind of directions that a grassroots evaluation of PAT could take by discussing salient social issues in the field, alongside examples of co-evaluators, and possible specific evaluation questions. We consider the *social issues* illustrative of the variety of concerns among different actors and commentators involved in the broad PAT space. The *example co-evaluators* are chosen to represent, as per the transformative paradigm, the expertise of the marginalized. As such they are people who we consider to be especially harmed by the social issue at hand, or to have expertise that is especially ignored or denigrated in relation to the social issue at hand. The *example questions*, while tentative and something to emerge and change through ongoing dialogue between co-evaluators (cf. Spriggs et al., 2023), are proposed in both a descriptive (“does”) and a speculative (“could”) format, in line with a transformative approach that aims not only to document what is but also to imagine – and move toward – what could be.

While we offer these directions, summarized in Table 1, in order to illustrate the potential of a grassroots approach, note that in practice these evaluations are not so linear. Typically they proceed in iterations and spirals through different stages of the process – including the identification of social issues, co-evaluators and questions – helping to ensure the response-ability of the evaluations themselves given the dynamic contexts within which they move.

Social atomization and apathy

The literature measuring changes in feelings of connectedness resulting from psychedelic experiences usually focuses on an



Table 1. Social issues that have been discussed in relation to PAT, with examples of key stakeholders to partner with in conducting evaluations, and examples of evaluation questions that might arise

Social Issues	Example Co-Evaluators	Example Evaluation Question
Social atomization, apathy	long-standing psychedelic group practitioners; experts in grassroots activism/community organizing acutely aware of its more embryonic processes	(How) does (or could) PAT lead to community and/or political organizing?
A harmful mental health system	mental health and psychiatric survivors; harm reduction peer movement; critical mental health professionals; psychiatry abolitionists	(How) does (or could) PAT help to combat iatrogenesis in mental healthcare?
Ongoing violence toward mad people	mad people; people diagnosed with psychotic disorder diagnoses; neurodivergent people; anti-stigma movement	(How) does (or could) PAT produce increased familiarity with and/or reduced stigma around psychosis/madness?
Cartesianism in healing	exiled, silenced, or criminalized healers – witches, shaman, tohunga; spokespersons for placebo; movements to increase mental health awareness	(How) does (or could) PAT be changing overall community-based understandings of healing, wellness, and transformation?
Climate change	Indigenous activists, climate refugees, climate justice activists	(How) does (or could) PAT affect people's relationship to the earth?
Anti-blackness, prohibitionism, and the 'War on Drugs'	those harmed by the war on drugs, discriminated against for their drug use, festival and party organizers, harm reduction service providers	(How) does (or could) PAT produce greater harm reduction infrastructure?
The dominance of the colonial episteme	indigenous experts, also more-than-humans (e.g. the land) & other-than-humans (e.g. plant spirits and teachers)	(How) does (or could) PAT help us to recognise and/or value what has been erased or denigrated through colonial processes?
Outmoded ways of knowing	movements for educational reform; disciplinary pariahs, students who feel discomfort about what they are learning, the usual 'objects' of disciplines	(How) does (or could) PAT improve the disciplines that study it?

individualized mode of administration (e.g., Watts et al., 2022). Against a backdrop of social atomization, isolation and apathy, as highlighted in critiques of neoliberalism and individualism (e.g. Davies et al., 2023), we can look into the growth and transformation of collectives, and/or their transformation into something more politicized, resulting from the sharing of psychedelic experiences. Arguments for the chemosocial nature of psychedelic experiences (Noorani et al., 2023) point to community and/or political organizing, ranging from wanting to connect over taboo, stigmatized, or denigrated experiences, to acquiring a “survivor mission” (Herman, 1998) to build the ‘psychedelic renaissance’ itself.

It is worth noting that this is precisely the kind of transformation that has been blamed for ending the ‘first’ wave of scientific research, with psychedelics ‘leaking’ out of their research containers and leading to countercultural projects to transform society (Giffort, 2020; Noorani, 2021). The idea that there were causal connections then presages the need to study them now. For such an evaluation from the grassroots, we might involve long-standing psychedelic group practitioners, and/or experts in community organizing and activism who are acutely aware of its more embryonic processes, and together develop an evaluation question such as, *(How) does (or could) PAT lead to community and/or political organizing?*

A harmful mental health system

A reduction in iatrogenesis – referring to harm caused by the mental healthcare system itself – has been one promise of

PAT for those critical of contemporary mental healthcare as too oriented around pharmacopeia (Noorani & Martell, 2021: 3). By and large, PAT has brought much further into the psychiatric debates than other recent drug-based interventions, conversations around relationality, care, and psychoactive substances as therapeutic adjuncts (for a prominent recent counter-example to the last, which drew six letters in response to its publication, see Goodwin, Malievskaia, Fonzo, & Nemeroff, 2023). A grassroots evaluation in response to this issue could partner with mental health and psychiatric survivors, harm reduction peers, mental health professionals critical of over-prescribing, and those seeking to abolish forced treatment in the mental healthcare system, in order to ask a question such as, *(How) does (or could) PAT help to combat iatrogenesis in mental healthcare?* Such an evaluation might also consider whether and how experts beyond therapists, such as Indigenous elders or spiritual chaplains, might be well-suited to hold people in and through the therapeutic use of psychedelic experiences.

Ongoing violence towards mad people

An important but sidelined question for psychedelic medicalization is whether the prevalence and normalization of PAT impacts movements to depathologise, destigmatise and/or better understand extreme states *not* produced through psychedelics – in particular, those understood through a biomedical lens as ‘psychosis’ or the family of ‘psychotic disorder’ diagnoses. One way to frame this



inquiry is in terms of the psychotomimetic theory that psychedelics can help engender more *empathy* with madness (Friessen, 2022; Noorani, 2022). This offers a different take on the liberatory impact of psychedelic normalization than the call for people with psychotic disorder diagnoses to not be excluded from trials (which by contrast might be considered as a form of PAT market expansion, thereby aligning more closely with Prilleltensky's above definition of 'co-optation'). A grassroots evaluation in relation to this kind of real-world impact of PAT could begin by partnering with people who identify as mad, or are diagnosed with psychotic disorder, bipolar disorder, or related, diagnoses, and neurodiversity and anti-stigma movements more broadly. An overarching question emerging from dialogue across co-evaluators might take the form, *(How) does (or could) PAT affect approaches to psychosis/madness?*

Reductionism in healing frameworks

The provision of healthcare in the Western epicenters of psychedelic medicalization – for instance, in the US, Western Europe and Australia – tend toward understandings of health and healing that are rooted in biological and neurological knowledge on the one hand, and psychological knowledge on the other. Meanwhile, the growing 'wellness' sector across these same places, often coded as 'complementary' and 'alternative' if not derided as 'snake oil', has been criticized for over-emphasizing the spiritual components of people's problems to the detriment of a proper accounting of biological, neurological and psychological elements (Welwood, 2000). Calls for 'integrative' (Lake, Helgason, & Sarris, 2012) and 'bio-psycho-social-spiritual' approaches remain marginal. However, such integration will not necessarily address a key underlying issue: the separation of mind, body and spirit. What new and renewed narratives and figures of healing does PAT bring to the fore, beyond the tendencies towards biological, psychological, and spiritual reductionism? In a grassroots evaluation of the effects of PAT upon these Cartesian inheritances undergirding approaches to healing, we could involve exiled, silenced, or criminalized figures of healing whose practices often cut across the siloes of biology, psychology, and spirituality, such as witches, shaman, and tohunga, together with experts in placebo. Such an evaluation might ask, *(How) does (or could) PAT change overall community-based understandings of healing, wellness, and transformation?*

Climate change

Whether through awareness of the relationship between healthy humans and ecological systems (e.g. Schaller & Sandu, 2011), the study of the phenomenology of nature-connectedness (e.g. Watts et al., 2022), or Indigenous knowledge systems (e.g. Kopenawa & Albert, 2013), psychedelics and more recently PAT have been associated with the urgent need for changed and new forms of collective consciousness around climate change. A grassroots evaluation of the extent to which PAT leads to such shifts in collective awareness and discussion could involve

Indigenous activists (including from the early environmental movement in the global North, which was closely entangled with the psychedelic counterculture), climate refugees, and climate justice activists and educators, to ask a question such as, *(How) does (or could) PAT affect people's relationship to the earth?*

Prohibitionism, the 'war on drugs', and anti-blackness

The revival of psychedelic science has been contextualized in terms of the history of drug prohibition, the 'war on drugs', and – particularly in the US context – an ongoing anti-Blackness. To understand the impact of the availability of PAT on this violence, one place to begin may be changes upon harm reduction and related decriminalization movements. Harm reduction is often understood in terms of product labelling information, but this overlooks the vital potential of collective changes such as nuanced policy reform (see for example, Transform, 2023), the availability of respite spaces, the provision of peer support lines (such as the Fireside Project in the US), one-to-one care services provided at festivals, and widespread public education and activist campaigns. A grassroots evaluation might seek to partner with those who have, for example, been harmed by the 'war on drugs' or discriminated against for their drug use, or providers of harm reduction services, organizers of psychedelic-friendly festivals, and activists toward prison abolition and/or Black liberation, to ask the question, *(How) does (or could) PAT reduce the harms of drug criminalisation?*

The dominance of the colonial episteme

There has been direct conversation between the transformative evaluation and the decolonising evaluation literatures (Cram & Mertens, 2016), which provides fertile scholarly soil for designing an evaluation that foregrounds (and disrupts) the dominance of the Euro-modern episteme in the development of PAT to date (see Celidwen et al., 2023; Schenberg & Gerber, 2022). For instance, we may attempt to trace PAT's effects on assumptions that agency and sentience reside in humans alone (Nayak, Singh, Yaden, & Griffiths, 2023), helping to bridge with Indigenous knowledge systems, or the dynamic relationship between changing 'mindsets', social transformation and resistance to oppression (Smith, 2009). For a grassroots evaluation in relation to the dominance of the colonial episteme, Indigenous experts would be crucial partners, and designs could also enfold the agency of non-humans (see also the section on *more-than-human hosting* below), in order to answer a question such as, *(How) does (or could) PAT uplift the authority of what has been denigrated or disappeared under colonialism?*

Outmoded ways of knowing

One thread for hopes for collective change consequent upon the acceptance of psychedelics into Western societies has rested in their potential to augment or radically transform the nature of education, (re)centering experience at the core



of learning (for example, Tupper, 2011) – indeed, arguably already observable in the debates over whether psychedelic therapists need to have had personal experiences with psychedelics (Dames, Kryskow, Watler, Pearl, & Allard, 2023). 1960s psychedelic iconoclast Timothy Leary captured something of this sentiment when he imagined a future when parents will ask their children as they return from college not what books they have read but what drugs they have taken. In relation to specific disciplines, psychedelics and PAT have given impetus to new or renewed discussion and innovation – for instance, in relation to clinical trial design, around unblinding and expectancy (Muthukumaraswamy, Forsyth, & Lumley, 2021; Szigeti & Heifets, 2024), and in relation to healthcare economics, measures of maximum health that go beyond the mere absence of disease symptoms (Marseille, Bertozzi, & Kahn, 2022). We may seek to document how the roll-out of PAT could change the very tools at our disposal for understanding psychedelics, PAT, and related phenomena. A grassroots evaluation could involve movements campaigning for educational reform, including through decolonisation, those with a critical relationship to their own disciplines, and historians of disciplines, as well as the usual ‘objects’ of disciplines – in the case of medicine, patients; in the case of pharmacology and botany, drugs and plants, and so forth – and ask, (*How*) does (*or could*) PAT transform the disciplines that study it?

THREE INTERRELATED VALUES OF A GRASSROOTS EVALUATION

As recommended by the transformative paradigm and modelled through a social movement that we find particularly inspiring (Matike Mai – see [\(The Independent Working Group on Constitutional Transformation, 2016\)](#)), our grassroots evaluation praxis is tethered to three interrelated values that we propose be used as lenses for decision-making throughout the entire evaluation process, from team-building and question generation through data collection and analysis, to dissemination. Taking inspiration from the capacious qualities of grass roots themselves, we call these values *rhizomatic accountability*, *dark reflexivity*, and *more-than-human hosting*.

Rhizomatic accountability

Rhizomatic accountability allows us to welcome not just the expert analyses of those who are (and that which is) most marginalized by social issues, but also the dynamic and plural nature of this expertise as it too shifts over time, space, and bodies. Such a rhizomatic – non-hierarchical, non-linear, multimodal – approach can be contrasted with simply ‘including’ representatives of communities in evaluations, which can risk essentializing and institutionalizing ‘marginalized voices’, thereby reproducing the historic irrelevance and/or violence of evaluations for marginalized communities (for example, Barnes, Henwood, Kerr, McManus, & McCreanor, 2011). A commitment to rhizomatic accountability resonates

with PAT given the increasing presence of those in mad justice and Indigenist movements who understand their oppression in terms of a pervasive epistemic injustice that cannot hear the legitimacy of their expertise (McMillan, 2022; Schenberg & Gerber, 2022).

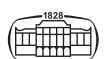
Rhizomatic accountability also echoes the relationship-building recognized as important in the effective administration of PAT. Indeed rhizomatic accountability further demands that we actively *tend* to ongoing relationships with relevant social movements. In the context of a transformative approach to evaluations, this means being accountable throughout the process – not just in formulating evaluation teams and questions, but co-creating methods of data collection, analysis, and dissemination outside of standard ‘academic’ formats and perhaps as interventions in the social issues in and of themselves (Kubala, 2023). We might invite people to ‘inter-view’ each other (Edwards, Carlson, & Liebert, 2023), entangling their perspectives, thereby strategically nourishing relationships; conduct ‘focus groups’ while doing something – collectively tending to plants or fungi, perhaps; and iterate between poesis (making art together, listening to music, dancing) and reflection-*cum*-analysis.

The recommendations of a grassroots evaluation could be made without any plan to universally scale the PAT interventions under evaluation, or otherwise fully apply them elsewhere, but with the aim of growing the transformative potential of the interventions as they are administered locally. Zelner (2020) has described the ‘Pollination Approach’ as cultivating local activity in and through PAT-administering centres, as a way to counter the extractivist tendencies of monopolistic capitalism and its mass scaling approach. As such, we consider the rhizomatic accountability of grassroots evaluations of PAT equivalent in terms of knowledge ecologies to what the Pollination Approach promises for geographically-local communities.

Dark reflexivity

Fanon (1952) articulates a version of reflexivity that encourages *both* evaluators *and* evaluatees to better appreciate how they are entangled with the ‘other’ they are working with – whether that be one another in the case of conducting an evaluation, or the clients and wider stakeholders of the evaluatees’ service(s) under evaluation. Attending to this entanglement increases the ability to attune to the wider social structures and relations of power within which we are all embedded, thereby strengthening structural analyses, while aligning with calls to intervene on saviourism – an ever-present risk in both evaluation work (Smith, 1999) and psychedelic ego-inflation. We suggest that reflexive practice calls for evaluators and evaluatees to ask of the social movements to which the evaluation and/or PAT administration is tethered, ‘How is *my* liberation also bound up with this?’ (Watson, 1985).

Many disciplinary approaches call for reflexivity as a core component in robust ways of knowing (e.g. Harding, 1993; Ruby, 1982). However, and just as roots grow in the dark, we call for grassroots evaluations to cultivate *dark reflexivity* as



a kind of reflexivity that grows in our *unknowing*. Here, we aim to become less – not more – comfortable (Pillow, 2003), as we come to learn the extent of what it is that we do not, and perhaps cannot – or even should not – know for sure (Glissant, 1997). Such an embrace of darkness resonates with the value afforded to the well-documented ineffability of the psychedelic experience, for example in terms of the generativity of the metaphors it affords (see Gearin, 2023) – a dark reflexivity toward unknowing can drive humble, response-able modes of knowing.

Dark reflexivity requires designing evaluations less to evaluate whether the explicit aims of PAT administration have been met, and more on PAT's current and potential effects – including the effects of the evaluation itself – ceding control but not response-ability (Alcoff, 1991). By not evaluating from a distance, 'over and above', but through being reflexively immersed in the very actions that it puts in place, grassroots evaluations build local resources and capacity as they proceed. Here, close to the ground if not underground, we cannot 'see' where exactly we are going, but our other senses, heightened, become our guides as we feel our way together (Tuck & Yang, 2012) – what Akomolafe and Ladha (2017) call an 'onto-epistemology of unknowing'. For example, evaluators and evaluatees might be encouraged to engage in experimental journaling throughout the process, by engaging the evaluators' own (biological, intellectual, activist, or other) ancestors, and ending always in questions. We understand such activities as a vital mode of enrichment of ongoing dialogue and conversation with the wider set of those who are affected by the issues and movements with which the evaluation engages.

More-than-human hosting

Lastly, our grassroots evaluations commit to experimenting with ways for collaborating with not just human but non-human stakeholders. By decentering the figure-*cum*-standard of the autogenic individual human at the center of colonial ways of knowing (Wynter, 2003), such experimentation aligns with calls for the decolonization of the psychedelic 'renaissance' and the strength of Indigenist movements within the Western psychedelic ecosystem. Nonetheless, there remains a risk of losing the liveliness of non-humans if simply 'capturing' them with our human gaze. Here we turn again to the grass roots, this time in their capacity as environments for non-humans to shelter – the roots themselves provide a structure that makes spaces, holds soil and prevents erosion. It is in this sheltering that we find guidance for undertaking a *more-than-human hosting* that is less about capturing and more about welcoming and nourishing the liveliness of non-humans (Liebert, 2018).

More-than-human hosting requires opening evaluation processes up to the various figures that (g)host PAT spaces, including through nurturing practices of working imaginatively. Such practices could include a commitment to mystery, ritual and pausing – explicitly compromising on certainty, repeating aesthetic gestures, and refusing quick

judgements or binaries – all thought to help make a space for more-than-human correspondence (Liebert, 2018). And all resonant with PAT given that it too can be approached as a kind of more-than-human hosting – whether of the substance itself or of the various agencies it engenders or encounters.

Grassroots evaluations are in some ways an attempt to uproot failing yet taken-for-granted approaches to producing evidence within PAT. If we do not experiment with ways of producing evidence that interrupt this legacy, we risk, even inadvertently, reproducing the real-world conditions that PAT has the potential to transform. For the same reasons, we recognize that this approach may feel – indeed, will be – difficult. It will come up against the very structures it is trying to transform in our communities, in our institutions, and in ourselves. While these are all moments of 'evaluation', grassroots evaluations require faith, stamina, and a collective – from our experience, these too all come from being in relationship with the grassroots.

CONCLUSION

The emerging delivery of PAT in test jurisdictions offers an opportunity to evaluate PAT in real-world contexts. The literature on transformative approaches fits well a shift from PAT evaluation designs that measure the amelioration of the treated individuals – the usual remit of RWE as captured through pharmacovigilance systems – to designs that measure collective changes and are committed to changing wider pathogenic conditions. We have described an approach we call a grassroots evaluation, which is predicated on the commitment that the most marginalized stakeholders and social movements relevant to the evaluation question are likely to have some of the most insightful analyses. Through examples of evaluation teams and questions that may be put to the real-world delivery of PAT, and the values of rhizomatic accountability, dark reflexivity and more-than-human hosting, we hope to generate discussion, innovation, and – ultimately – action toward specific study designs that are adequate to the task of documenting, and working with, the transformative potential of psychedelics in contemporary medicalized societies.

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REFERENCES

- Aaron, D. (2023). The fall of FDA review. *Yale Journal of Health Policy, Law, and Ethics*.
- Akomolafe, B., & Ladha, A. (2017). Perverse particles, entangled monsters and psychedelic pilgrimages: Emergence as an onto-epistemology of not-knowing. *ephemera: Theory & Politics in Organization*, 17(4).
- Alcoff, L. (1991). The problem of speaking for others. *Cultural Critique*, (20), 5–32.
- Bache, C., Versluis, A., & Shipley, M. (2019). Conversation with Christopher Bache. *Journal for the Study of Radicalism*, 13(1), 155–178. <https://doi.org/10.14321/jstudradi.13.1.0155>.
- Barnes, J. (2022). Advances in methods and techniques in pharmacovigilance for herbal and traditional medicines and other natural health products. *Pharmacovigilance for Herbal and Traditional Medicines: Advances, Challenges and International Perspectives*, 93–139.
- Barnes, H. M., Henwood, W., Kerr, S., McManus, S. V., & McCreanor, T. (2011). Knowledge translation and indigenous research. In E. M. Banister, B. J. Leadbeater, & E. A. Marshall (Eds.), *Knowledge translation in context: Indigenous, policy, and community settings* (pp. 161–180). University of Toronto Press.
- Brennan, B. (2020). The revolution will not be psychologized: Psychedelics' potential for systemic change. *Chacruna*. Available at: <https://chacruna.net/the-revolution-will-not-be-psychologized-psychedelics-potential-for-systemic-change/> (last accessed December 30th, 2023).
- Carhart-Harris, R. L., Wagner, A. C., Agrawal, M., Kettner, H., Rosenbaum, J. F., Gazzaley, A., ... Erritzoe, D. (2022). Can pragmatic research, real-world data and digital technologies aid the development of psychedelic medicine? *Journal of Psychopharmacology*, 36(1), 6–11.
- Celidwen, Y., Redvers, N., Githaiga, C., Calambás, J., Añaños, K., Chindoy, M. E., ... Sacbajá, A. (2023). Ethical principles of traditional indigenous medicine to guide western psychedelic research and practice. *The Lancet Regional Health–Americas*, 18.
- Cram, F., & Mertens, D. (2016). Negotiating solidarity between indigenous and transformative paradigms in evaluation. *Evaluation Matters–He Take Tō Te Aromatawai*, 2(2), 161–189.
- Dames, S., Kryskow, P., Watler, C., Pearl, T., & Allard, P. (2023). Psychedelic-assisted Therapy Training: First Hand experience of non-ordinary states of consciousness in the pursuit of competency. *Unpublished manuscript*. https://rootstothrive.com/wp-content/uploads/2023/01/Psychedelic-Therapy-Education_-Is-the-Experience-of-Psychedelic-Therapy-a-Necessary-Competency-Standard-for-those-Training-to-Provide-Psychedelic-Therapists_.pdf.
- Davies, J., Pace, B. A., & Devenot, N. (2023). Beyond the psychedelic hype: Exploring the persistence of the neoliberal paradigm. *Journal of Psychedelic Studies*, 8(2).
- Edwards, R., Carlson, T., & Liebert, R. (2023). Decolonising interview methods: A call to look to the moon. *Times Higher Education*. <https://www.timeshighereducation.com/campus/decolonising-interview-methods-call-look-moon>.
- Eisner, B. (1997). Set, setting, and matrix. *Journal of Psychoactive Drugs*, 29(2), 213–216. <https://doi.org/10.1080/02791072.1997.10400190>.
- Fanon, F. (1952). *Black skin, white masks*. Paris: Editions du Seuil.
- Friesen, P. (2022). Psychosis and psychedelics: Historical entanglements and contemporary contrasts. *Transcultural Psychiatry*, 59(5), 592–609. <https://doi.org/10.1177/13634615221129116>.
- Gearin, A. K. (2023). Moving beyond a figurative psychedelic literacy: Metaphors of psychiatric symptoms in ayahuasca narratives. *Social Science & Medicine*, 334, 116171.
- Giffort, Danielle (2020). *Acid revival: The psychedelic renaissance and the quest for medical legitimacy*. Minnesota: University of Minnesota Press.
- Glissant, É. (1997). *Poetics of relation*. University of Michigan Press.
- Goodwin, G. M., Malievskaia, E., Fonzo, G. A., & Nemeroff, C. B. (2023). Must psilocybin always “assist psychotherapy”? *American Journal of Psychiatry*, appi-ajp.
- Harding, S. (1993). Rethinking standpoint epistemology: What is strong objectivity? In *Feminist epistemologies* (pp. 49–82). New York and London: Routledge.
- Healy, D. (2021). *Shipwreck of the singular: Healthcare's castaways*. Samizdat Health Writer's Co-operative Incorporated.
- Healy, D., & Mangin, D. (2019). Clinical judgments, not algorithms, are key to patient safety—an essay by David Healy and Dee Mangin. *BMJ (Clinical Research ed.)*, 367, 15777. <https://doi.org/10.1136/bmj.15777>.
- Herman, J. (1998). Recovery from psychological trauma. *Psychiatry and Clinical Neurosciences*, 52(S1), S98–S103.
- Herxheimer, A., Comburg, R., & Alves, T. (2010). *Direct patient reporting of adverse drug events*. Briefing Paper. Amsterdam: Health Action International.
- Kopenawa, D., & Albert, B. (2013). *The falling sky: Words of a Yanomami shaman*. Harvard University Press.
- Kubala, P. (2023). Songs of life: Psychedelic-assisted psychotherapy and Deleuze and Guattari's 'desiring-production'. *Deleuze and Guattari Studies*, 17(4), 482–505.
- Lake, J., Helgason, C., & Sarris, J. (2012). Integrative mental health (IMH): Paradigm, research, and clinical practice. *Explore*, 8(1), 50–57.
- Lentacker, A. (2024). Epistemology of the side effect: Anecdote and evidence in the digital age. *BioSocieties*, 19, 84–111. <https://doi.org/10.1057/s41292-022-00293-5>.
- Liebert, R. J. (2018). *Psycurity: Colonialism, paranoia, and the war on imagination*. Routledge.
- Marseille, E., Bertozzi, S., & Kahn, J. G. (2022). The economics of psychedelic-assisted therapies: A research agenda. *Frontiers in Psychiatry*, 13, 1025726. <https://doi.org/10.3389/fpsy.2022.1025726>.
- McMillan, R. M. (2022). Psychedelic injustice: Should bioethics tune in to the voices of psychedelic-using communities? *Medical Humanities*.
- Mertens, D. M. (1999). Inclusive evaluation: Implications of transformative theory for evaluation. *American Journal of Evaluation*, 20(1), 1–14.



- Mertens, D. M. (2008). *Transformative research and evaluation*. Guilford press.
- Muthukumaraswamy, S. D., Forsyth, A., & Lumley, T. (2021). Blinding and expectancy confounds in psychedelic randomized controlled trials. *Expert Review of Clinical Pharmacology*, 14(9), 1133–1152.
- Nayak, S. M., Singh, M., Yaden, D. B., & Griffiths, R. R. (2023). Belief changes associated with psychedelic use. *Journal of Psychopharmacology*, 37(1), 80–92. <https://doi.org/10.1177/02698811221131989>.
- Noorani, T. (2021). Containment matters: Set and setting in contemporary psychedelic psychiatry. *Philosophy, Psychiatry, & Psychology*, 28(3), 201–216.
- Noorani, T. (2022). Between a rock and a hard place: Psychotomimesis in psychedelic science. In *Breaking convention: A seismic shift in psychedelia* (pp. 60–74). London, UK: Strange Attractor Press.
- Noorani, T., Bedi, G., & Muthukumaraswamy, S. (2023). Dark loops: Contagion effects, consistency and chemosocial matrices in psychedelic-assisted therapy trials. *Psychological Medicine*, 1–10.
- Noorani, T., & Martell, J. (2021). New frontiers or a bursting bubble? Psychedelic therapy beyond the dichotomy. *Frontiers in Psychiatry*, 12, 727050.
- Pillow, W. (2003). Confession, catharsis, or cure? Rethinking the uses of reflexivity as methodological power in qualitative research. *International Journal of Qualitative Studies in Education*, 16(2), 175–196.
- Plesa, P., & Petranker, R. (2023). Psychedelics and neoliberalism: Connectedness in a meaningless world. *Frontiers in Psychology*, 14, 1125780. <https://doi.org/10.3389/fpsyg.2023.1125780>.
- Prilleltensky, I. (2014). Meaning-making, mattering, and thriving in community psychology: From co-optation to amelioration and transformation. *Intervención Psicosocial*, 23(2), 151.
- Ruby, J. (Ed.). (1982). *A crack in the mirror: Reflexive perspectives in anthropology*. University of Pennsylvania Press.
- Schaller, B., & Sandu, N. (2011). Clinical medicine, public health and ecological health: A new basis for education and prevention? *Archives of Medical Science*, 7(4), 541–545.
- Schenberg, E. E., & Gerber, K. (2022). Overcoming epistemic injustices in the biomedical study of ayahuasca: Towards ethical and sustainable regulation. *Transcultural Psychiatry*, 59(5), 610–624.
- Skivington, K., Matthews, L., Simpson, S., Craig, P., Baird, J., Blazeby, J. M., ... Moore, L., L. (2021). A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance. *BMJ (Clinical Research Ed.)*, 374(n2061). <https://doi.org/10.1136/bmj.n2061>.
- Smith, G. H. (2009). Mai i te maramatanga, ki te putanga mai o te tauritanga: From conscientization to transformation. In *Social justice, peace, and environmental education* (pp. 31–40). Routledge.
- Smith, L. (1999). *Decolonizing research: Indigenous storywork as methodology*. Bloomsbury Publishing.
- Spriggs, M. J., Murphy-Beiner, A., Murphy, R., Bornemann, J., Thurgur, H., & Schlag, A. K. (2023). A: A framework for access, reciprocity and conduct in psychedelic therapies. *Frontiers in Psychology*, 14, 1119115.
- Szigei, B., & Heifets, B. D. (2024). Expectancy effects in psychedelic trials. *Biological Psychiatry. Cognitive Neuroscience and Neuroimaging*, S2451-9022(24)00055-7. Advance online publication. <https://doi.org/10.1016/j.bpsc.2024.02.004>.
- The Independent Working Group on Constitutional Transformation. (2016). *Matike Mai Aotearoa: He Whakaaro Here Whakaumu Mō Aotearoa*. Self-published. <http://www.converge.org.nz/pma/MatikeMaiAotearoaReport.pdf>.
- Transform (2023). *How to regulate psychedelics: A practical guide*. Transform Drug Policy Foundation.
- Tuck, E., & Yang, K. W. (2012). Decolonization is not a metaphor. *Decolonization: Indigeneity, Education & Society*, 1(1), 1–40.
- Tupper, K. W. (2011). *Ayahuasca, entheogenic education & public policy*. Doctoral dissertation. University of British Columbia.
- Watson, L. (1985). *Quote taken from a speech given at the United Nations decade for women conference*. Nairobi.
- Watts, R., Kettner, H., Geerts, D., Gandy, S., Kartner, L., Mertens, L., ... Roseman, L. (2022). The Watts connectedness scale: A new scale for measuring a sense of connectedness to self, others, and world. *Psychopharmacology*, 239(11), 3461–3483. <https://doi.org/10.1007/s00213-022-06187-5>.
- Welwood, J. (2000). *Toward a psychology of awakening: Buddhism, psychotherapy, and the path of personal and spiritual transformation*. Boston, MA: Shambhala.
- Wynter, S. (2003). Unsettling the coloniality of being/power/truth/freedom: Towards the human, after man, its overrepresentation - An argument. *CR: The New Centennial Review*, 3(3), 257–337.
- Zelner, B. (2020). The pollination approach to delivering psychedelic-assisted mental healthcare. *MAPS Bulletin Spring*, 30, 34–37.

