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Psychedelic-assisted therapies
The past, and the need to move forward responsibly

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Abstract

Recent clinical studies illustrate that psychedelics such as LSD and psilocybin may represent much-needed new treatment options for mood disorders and alcohol and other drug use disorders. More clinical studies are required to confirm the safety and efficacy of psychedelic-assisted therapies, but the cultural stigma that has surrounded psychedelics since the 1960s has hindered research. This problem is amplified in Australia. There has been a complete absence of clinical studies into psychedelic therapies, and Australian-based research advocates claim to have encountered a number of barriers. In this commentary, we provide a brief account of the historical stigma associated with psychedelics, and an overview of the contemporary context of research into psychedelic-assisted therapies, including the purported barriers to research in Australia. In light of the complex history of psychedelics, we identify a number of pressing questions relating to the social and legal context that need to be addressed so that clinical studies can proceed. Research is needed to address such questions so that the nature and extent of purported barriers to clinical studies with psychedelics can be properly elucidated, and strategies developed – with practitioners, patients, families and other stakeholders – to responsibly address these barriers. This is important because it will enable Australian researchers to contribute robust evidence about the possible efficacy and safety of psychedelic therapies, and to facilitate local expertise needed to implement psychedelic-assisted therapies, should they prove efficacious.

Introduction

Mood disorders (e.g., depression, anxiety, PTSD) and alcohol and other drug use disorders place a large burden on the individual, families and healthcare systems, and are a significant economic cost in Australia and elsewhere (GBD 2015 Neurological Disorders Collaborator Group, 2017). New and more effective therapies are needed, particularly for those who do not respond to current treatments (Al-Harbi, 2012). Researchers and clinicians have begun exploring the therapeutic potential of psychedelic compounds to treat addiction and mood disorders (Robin L. Carhart-Harris & Goodwin, 2017; Franz X. Vollenweider & Kometer, 2010). These include compounds such as psilocybin, lysergic acid diethylamide (LSD), and ayahuasca, which induce altered states of consciousness by acting on the brain's 5-HT2A receptors (i.e. those compounds conventionally defined as 'psychedelic'), and also 3,4-Methylenedioxymethamphetamine (MDMA) that has 'mind altering' effects via a different neurochemical pathway. Initial research interest in the therapeutic use of these compounds began in 1950s but was soon curtailed for political, social, and subsequent legal reasons (Stevens, 1987). The current resurgence of research on the efficacy of these compounds is in its infancy, but preliminary findings are encouraging: some therapeutic benefit has been demonstrated for indications such as major depressive disorder, post-traumatic stress disorder (PTSD), obsessive-compulsive disorder (OCD), anxiety associated with life threatening illness, alcohol dependence, and long-term tobacco smoking, and risks of toxicity and dependency appear to be low (Elsey, 2017; Ivan Ezquerra-Romano, Lawn, Krupitsky, & Morgan, 2018). Experts are calling for further studies – particularly controlled trials – to confirm these preliminary but promising findings (de Veen, Schellekens, Verheij, & Homberg, 2017). In order to fast track such studies, the US Food & Drug Administration recently granted 'breakthrough therapy' status to psilocybin for the treatment of depression (Rahhal, 2018), and MDMA for the treatment of PTSD (MAPS, 2017a).

Much of this 'second wave' of research has taken place in leading academic centers in the US and Europe, including Imperial College London and Johns Hopkins University (Robin L. Carhart-Harris & Goodwin, 2017). There has, however, been a notable absence of research into psychedelic-assisted therapies in Australia. Australian-based advocates argue that research has been hindered by

the stigma associated with psychedelics since the 1960s. As some commentators lamented, "Australia risks being left behind… [leaving] Australian psychiatrists and psychologists without opportunities to trial treatments that may benefit many Australians" (Strauss, Bright, & Williams, 2016, p. 1037).

Given the urgent need for new interventions that are more effective in managing mood disorders and substance misuse, it is concerning that research into psychedelic-assisted therapies may be prevented by conservative or ill-informed attitudes. In this piece, we provide a brief account of the historical stigma associated with psychedelics, and an overview of the contemporary context of research into psychedelic-assisted therapies, including the purported barriers to research in Australia. In light of the complex social and political history of psychedelics, we identify a number of pressing questions that need to be addressed so that research can proceed. These questions specifically relate to the current social and legal context of psychedelic research in Australia. Research is needed to address such questions so that the nature and extent of purported barriers to research can be properly elucidated, and strategies developed – with practitioners, patients, families and other stakeholders – to address these barriers. This is important because it will enable Australian researchers to contribute robust evidence about the possible efficacy and safety of psychedelic therapies, and to facilitate local expertise needed to implement psychedelic-assisted therapies, should they prove efficacious.

A brief history: early therapeutic use and the political backlash

Plant-derived psychedelics have been used in religious practices and traditional healing in some cultures for thousands of years (Hofmann, 2005). It was in the early 1950s, however, that psychologists and psychiatrists first became interested in the therapeutic potential of psychedelics. This interest was prompted by emerging reports of the subjective effects of lysergic acid diethylamide (LSD) which was first synthesized in 1943 (Robin L. Carhart-Harris & Goodwin, 2017). In North America, Europe, and the UK, LSD was adopted within 'psycholytic' or 'psychedelic psychotherapies' for mood disorders and alcoholism throughout the 1950s. It is estimated that over a period of 15 years, tens of thousands of people were treated with these therapies (Caldwell, 1969; Grinspoon & Bakalar, 1997). In

Saskatchewan, Canada, for example, psychedelic therapy became a standard treatment for alcoholism (Dyck, 2006). Scientific studies on the therapeutic effects of psychedelics were undertaken until the 1970s (the most notable being the Spring Grove Experiments in Catonsville, Maryland). The results from these studies were promising, but the small sample sizes and poor study design significantly limit the claims that can be made about the clinical utility of psychedelic substances (Nichols, 2016). Many of these early studies, for example, lacked control participants and did not employ randomization, and there was an absence of standardized diagnostic techniques and assessment tools (Robin L. Carhart-Harris & Goodwin, 2017).

Recreational consumption of LSD famously flourished in the 1960s amongst the counter-cultural movement. By the late 1960s, the political backlash against the movement included an explicit condemnation of LSD, which was described as having a corrosive effect on Western values (Franz X. Vollenweider & Kometer, 2010). LSD became the subject of alarmist mass media attention including claims that it caused insanity, chromosomal damage, and that it convinced users they could fly (Nichols, 2016; Siff, 2015). These messages were highly influential in shaping the opinions of the general public. In 1965 psychedelics were listed as prohibited substances in the US and were removed from legal circulation. In 1970, President Nixon signed the Controlled Substances Act, in which LSD and psilocybin were listed 'Schedule 1', the most restrictive category for drugs with high abuse potential and no medical use, despite no evidence that it was addictive (Stevens, 1987). Similar changes followed in the UK and Europe, and as a result, research into psychedelic-assisted therapies was effectively brought to a halt.

The contemporary context

Interest in psychedelic research was renewed in the 1990s by scientists in Europe and the US exploring the psychopharmacological effect of psychedelics in healthy individuals (Hermle et al., 1992; Strassman & Qualls, 1994; F. X. Vollenweider et al., 1997). Promising results from a number of subsequent psychopharmacological, psychological and neuroimaging studies, prompted a handful of

early phase clinical trials of psychedelic-assisted therapies for mood disorders or addictions in the 2000s (Robin L. Carhart-Harris & Goodwin, 2017). Between 2001 and 2004, a proof-of-concept study of psilocybin-assisted therapy in nine patients with obsessive-compulsive disorder found no significant adverse events, and a significant decrease in OCD symptoms in the small sample at the final endpoint 24 hours after the therapy session (Moreno, Wiegand, Taitano, & Delgado, 2006). Pilot studies of psychedelic-assisted therapies for anxiety associated with life-threatening illness have also produced promising results. Two double-blind, randomized controlled trials, both involving 12 patients (one trial using psilocybin and the other using LSD), found no major adverse effects and a marked reduction in anxiety that was sustained throughout the 12-month follow-up period (Gasser et al., 2014; Grob et al., 2011). Similarly, a double-blind controlled trial of psilocybin in 29 patients with advanced-stage cancer found enduring anxiety-reducing and anti-depressive effects in 60-80% of participants at six-month follow-up (Ross et al., 2016). Psilocybin-assisted psychotherapies for treatment-resistant depression have also shown promise. In an open-label study at Imperial College London, 20 participants were given two doses of psilocybin seven days apart. The 19 patients who completed follow-up assessments experienced a reduction in depression at one week, with nine patients showing a significant response at week five. Significant reductions in depressive measures were observed at the final six-month follow-up. (R. L. Carhart-Harris et al., 2018). Open-label trials of psilocybin treatments for alcohol and tobacco addiction have also shown positive results. A study involving ten patients with alcohol dependence demonstrated a significant increase in abstinence that was largely retained at the 36-week follow-up (Bogenschutz et al., 2015). While in a study of 15 nicotine-dependent smokers, 12 participants demonstrated abstinence at the six-month follow-up (M. W. Johnson, Garcia-Romeu, Cosimano, & Griffiths, 2014).

While all these trials have demonstrated some therapeutic benefits and no major adverse events, they involved small sample sizes that approximate what would conventionally be described as 'safety and tolerability' studies (Robin L. Carhart-Harris & Goodwin, 2017). In 2018, just over 20 clinical trials involving psilocybin or LSD for therapeutic use are listed in the US Government and

European Union clinical trials registries. These are mostly phase two trials for the health conditions listed above, as well as for cocaine-related disorders, cluster headaches, and migraine headaches.

There are a number of likely reasons for the re-emergence of research on psychedelic-assisted therapies. The acute awareness among research and clinical communities that more effective treatments are desperately needed is no doubt one of these (Al-Harbi, 2012). The political climate around the use of these compounds has also changed. While the countercultural movement still features heavily in the public imagination, its potency as a genuinely radical political force has long since dissipated. The so-called 'war on drugs' is now considered by many to be a failure (Shultz & Aspe, 2017), and there have been substantial moves towards more liberal drug policies in some countries (e.g. US, Canada, Uruguay). There has been, for example, a growing number of studies examining the clinical benefit of cannabis for a wide range of medical conditions, albeit with mixed results. Social and political concern with PTSD among returned service people and first responders (for which MDMA has shown some promise), is likely to have been another factor. Consequently, in the present climate authorities may now be more inclined to issue researchers with the permits that are required for the manufacturing, sale, storage or use of psilocybin, LSD and other prohibited drugs such as MDMA (Simon, 2018).

The socio-political context is also populated with advocacy groups promoting medical research on the therapeutic benefits of psychedelics and MDMA. This includes the Californian-based (but internationally active) Multidisciplinary Association for Psychedelic Studies (MAPS), which describes itself as a "research and education organization", and which is sponsoring clinical trials on the LSD-assisted psychotherapy for anxiety associated with life-threatening illness, MDMA-assisted psychotherapy for post-traumatic stress disorder, and ibogaine therapy for drug addiction (MAPS, 2017b). Similarly, the Heffter Research Institute, which has close ties with Johns Hopkins University and other academic research centres, is actively involved in designing and funding research into psychedelics. It is currently seeking to fund clinical studies of psilocybin for the treatment of anorexia nervosa, opioid dependence, depression, and PTSD ("Hefter Research Institute," 2018). These and

other advocacy organizations have been pivotal in securing the philanthropic support needed to conduct psychedelic research. This has been necessary, commentators have argued, because pharmaceutical companies have been reluctant to invest given that the proposed treatment model (which involves only two or three dosings) does not align with their dominant business model of prolonged treatment (Strauss et al., 2016).

The absence of such studies in Australia has been lamented by some researchers (Strauss et al., 2016) and recent media coverage (Gelfer, 2014; Siddique, 2017; Ten News, 2016). Researchers from the Australian-based Psychedelic Research in Science & Medicine (PRISM) – a clinical research organization – have been particularly vocal in identifying what they believe to be several barriers to research, based on their own experiences of attempting to initiate research (Bright & Williams, 2018; Bright, Williams, & Caldicott, 2017; Strauss et al., 2016). They argue, for example, that there is an "entrenched conservativism and risk-aversion in the Australian research community" (Bright & Williams, 2018, p. 472). Research institutions – particularly universities – are reluctant to become involved in potentially controversial research that could tarnish reputations: a PRISM-supported clinical trial for of MDMA-assisted psychotherapy for the treatment of PTSD among war veterans was vetoed by the Deputy Vice-Chancellor at a Victorian university (Bright et al., 2017). The Australian research community is also highly dependent on competitive government funding which is unlikely to support unconventional, 'risky' research (Bright & Williams, 2018, p. 472), and there are very few other funding options available for psychedelic research in Australia (Inserra, 2019). PRISM researchers suggest that research ethics committees have been inclined to take a highly conservative approach, despite the demonstrated safety profile of the psychedelic compounds in question (Strauss et al., 2016). It has also been suggested that there is a general ignorance about psychedelics within the wider medical establishment in Australia, particularly among frontline mental health and medical practitioners (Puspanathan, 2017). PRSIM researchers have argued that some practitioners and members of the Australian research community have "vested interests in maintaining the status quo" and are unwilling to recognise the limitations of current "gold standard" treatments (e.g. Cognitive

Behavioural Therapy) or to question the dominant paradigm that illicit drugs such as LSD are hazardous and require prohibition (Bright & Williams, 2018, p. 472). There may also be concern among some researchers and clinicians that governments would block controversial trials. Indeed there is precedent for this happening in Australia: in 1997, the Howard government prevented a trial of prescribed heroin to a small number of individuals who had failed all other medical interventions (Mendes, 2001). Consequently, much of the Australian clinical research experience moved over to the UK where a trial of prescribed heroin was conducted providing the first positive evidence in a UK RCT of injectable heroin (Strang et al., 2010).

Moving forward responsibly

There is a great need for new treatments for mood disorders and alcohol and other drug problems, and because of the promising findings emerging from early phase clinical studies overseas, Australian-based research into psychedelics should not be prevented on the basis of stigma, history and ill-informed attitudes. Aside from contributing much-needed data on efficacy and safety of psychedelic therapies, Australian-based research will provide psychiatrists and psychologists with an opportunity to trial treatments. This is necessary for building the institutional expertise needed to successfully implement psychedelic-assisted therapies more widely should studies demonstrate their safety and efficacy. It is also important that practitioners have the opportunity to identify the appropriate psychotherapeutic settings for diverse Australian patients.

Commentators have suggested that a greater understanding of the effectiveness of psychedelic compounds at the molecular level will persuade funding bodies and academic institutions to support research into psychedelic-assisted therapies (e.g. Inserra, 2019). However, Science and Technology Studies (STS) research into medical and healthcare innovations has noted that a favorable safety, efficacy and cost-effectiveness profile of a therapeutic intervention is not, on its own, sufficient to guarantee its ongoing development or eventual implementation within clinical practice. The priorities of institutions, the interests and viewpoints of researchers and professional groups, and the wider

political climate can represent formidable barriers to innovation, even for highly promising interventions (John Gardner, Higham, Faulkner, & Webster, 2017; J. Gardner, Webster, & Barry, 2018). Hence, we suggest that it is necessary to comprehensively investigate whether the socio-cultural barriers identified by advocates do indeed exist in Australia, and if they do, to identify ways in which such barriers can be responsibly managed.

There are pressing questions relating to the use of psychedelics that need to be actively addressed, beyond those relating to the safety and efficacy of psychedelic compounds. First and foremost, how receptive are Australian publics - and especially afflicted individuals and their families – to the possibility of psychedelic-assisted therapies? How, for example, might the potential of psychedelics to induce what are often described as 'mystical experiences' accord with the religious and cultural perspectives of Australian publics? Equally important are the views and perspectives of frontline health professionals. What are their concerns relating to their use, and more generally, what capacity is there in Australia for implementing psychedelic assisted therapies? The institutional requirements for implementation may represent a significant hurdle: current clinical studies involve a therapy session that lasts up to eight hours, and involve two therapists or 'monitors' who have "significant human relation skills" and who are ideally "familiar with descriptions of altered states of consciousness" (M. Johnson, Richards, & Griffiths, 2008). Another important question here relates to the primacy of the session's 'set and setting' for configuring a therapeutic response. The current standard in contemporary studies involves a 'living-room' type arrangement and a carefully prepared music playlist that includes classical music (M. Johnson et al., 2008; Kaelen et al., 2018). Such western-centric 'set and setting' configurations may not be appropriate for all health care recipients in a population as diverse as Australia's. How, then, might Australian healthcare professionals go about creating more tailored, culturally-relevant 'set and setting' configurations?

The legal classification of psilocybin, LSD and other hallucinogens as prohibited drugs also raises important questions. Finding a suitable supplier for a clinical-grade psychedelics for research purposes is already a known problem (Wong, 2013), but how might regulators respond to a permit

request to undertake research involving psilocybin? What considerations are likely to shape their decision-making? Additionally, can we learn anything from recent legislative developments – such as the passing of Victoria's *Access to Medicinal Cannabis Act* (2016) – for facilitating medicinal access to psychedelic compounds, should they be proven safe and effective?

The potential negative impact of hype also needs to be monitored. The emergence of over-optimistic portrayals of psychedelics in the public realm remains a very real possibility, especially given the highly active role of advocacy groups and recent positive media coverage. Already private operators are seeking to capitalize on the positive messages surrounding psychedelic compounds: 'detox' clinics are advertising expensive and unproven Ibogaine therapies at luxury health resorts in Mexico, Thailand, and other countries where the substance has not been prohibited (Carter & Hall, 2011). How, then, might the findings of legitimate research be clearly communicated to the public in an era when health-related information is produced and circulated by numerous sources?

The history of psychedelic research provides a stark reminder of how scientific endeavor can be stunted by socio-political factors. Psychedelics are politically and culturally loaded, and the result of this is that we are bereft of a much-needed body of evidence on their therapeutic capacity. Addressing the questions such as those discussed here can help 'prepare the ground' for responsible research into psychedelic-assisted therapies, and indeed other therapies using prohibited drugs. We believe that to do so requires a multidisciplinary approach that draws extensively on the social sciences, particularly sociology, STS, socio-legal studies and neuroethics. These disciplines have a rich heritage of investigating the socio-political dimensions of science, as well as expertise in actively engaging with health service providers, patient and consumer groups, and publics.

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