UK Parliament
POST

POSTbrief 64

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12 February 2025

Psychedelic-assisted therapy for mental health: Policy considerations

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Suggested citation

Chapman, J. and Naulls, S. (2025) *Psychedelic-assisted therapy for mental health: policy considerations.* Parliamentary Office of Science and Technology

DOI: https://doi.org/10.58248/PB64

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Overview

- A growing number of clinical trials have shown that psychedelic drugs (such as LSD and ketamine), in combination with therapy, can be used to treat mental health conditions, such as post-traumatic stress disorder (PTSD) and depression. This approach is called psychedelic-assisted therapy (PAT).
- Psychedelic drugs are legally controlled. Except for ketamine, they are in schedule 1 under the Misuse of Drugs Regulations 2001. Drugs in schedule 1 have no recognised medicinal use.
- Schedule 1 drugs have the greatest restrictions on research into their medical potential. Research in universities and hospitals requires a Home Office licence. Home Office licensing requirements can make conducting clinical trials using psychedelic drugs expensive, time-consuming, and logistically difficult.
- Academic researchers, mental health charities, patients, and some MPs have called for certain schedule 1 psychedelic drugs to be moved into schedule 2, while retaining their status as class A drugs, to remove barriers to clinical trials. They argued that some evidence showed the medicinal potential of psychedelic drugs, and therefore their schedule 1 status is no longer appropriate.
- Some policymakers have stated that legitimate research with psychedelic drugs must ensure that the drugs are not diverted or misused. Others are concerned that negative effects experienced by some recreational psychedelic drug users will also occur during therapy.
- In 2022, the government said in response to a petition that there were no plans to move psilocybin, the psychedelic substance in 'magic mushrooms', to schedule 2.
- A 2023 Home Affairs Committee report recommended "urgent" rescheduling of psychedelic drugs to enable larger clinical trials to take place, to better understand the safety and efficacy of PAT.
- The government responded by commissioning the Advisory Council on the Misuse of Drugs (ACMD) to consider "barriers to research". In 2023, the ACMD published a report which evaluated ways to make research with schedule 1 drugs, including PAT clinical trials, easier to conduct. The report discussed the implications of rescheduling some schedule 1 drugs. As of February 2025, the government is yet to respond to the ACMD report.
- POST published Rapid Response articles in 2023 and 2024 summarising the evidence base for PAT in the treatment of addiction, eating disorders, PTSD, anxiety disorders and depression.

1 Background

Psychedelic drugs, such as LSD, DMT,[a] ketamine, MDMA ('ecstasy') and psilocybin,[b] have a range of effects on the brain.[c 5] This can include temporary changes in mood, perception and thought processes.[5] Many psychedelic drugs have a history of use in spiritual, recreational and therapeutic settings.[6]

Research into the therapeutic potential of psychedelic drugs took place in the 1950s and 1960s.[3,5,7] Almost all research stopped in the 1970s, mostly due to tightening drugs legislation.[7] Since the 2000s there has been a resurgence of interest in investigating how psychedelic drugs can treat mental health conditions using modern scientific methods.[8]

This briefing focuses on the risks and benefits of supervised therapy using psychedelic drugs in controlled clinical settings.

1.1 Psychedelic-assisted therapy

Controlled clinical trials are investigating how some psychedelic drugs, in combination with therapy, can be used to treat patients with specific mental health conditions.[9] This treatment is called psychedelic-assisted therapy, or PAT.

The stages of PAT are outlined in box 1 below. Some clinical trials have been conducted in UK universities and hospitals, with some funding coming from UK Government grants.[10]

Box 1: Stages in psychedelic-assisted therapy (PAT) clinical trials

Clinical trials investigating the safety and efficacy of psychedelic drugs as a treatment for mental health conditions have focused on PAT, which generally involves:

[a] DMT (N,N-Dimethyltryptamine) is a psychedelic drug with a long history of use in some indigenous communities.[1]

[b] Psilocybin, an inert chemical found in 'magic mushrooms', is converted into psilocin in the body. Psilocin is a psychoactive compound.[2]

[c] Definitions of 'psychedelic' drugs vary.[3] Some researchers do not consider ketamine and MDMA to be psychedelic drugs.[4]

1. Screening: patients meet with trained medical professionals. They review any prescribed medications and determine if the patient has a history of schizophrenia, psychosis, or mania, or if there is a family history of these conditions.[11,12] They also check patients' cardiovascular (heart and blood vessel) health.[13,14] Patients with these medical histories are excluded from PAT clinical trials.[15]
2. Preparation: patients and clinicians build a relationship.[16,17] They discuss what the psychedelic experience may entail to minimise potential anxiety and maximise the value of the experience.[16,18]
3. Psychedelic experience: patients take the psychedelic drug under medical supervision in the hospital or university.[3] The psychedelic experience can last up to eight hours, during which psychological support is offered.[19] The patient may choose to talk about their mental health during this time.[20]
4. Integration: patients meet their therapist to discuss insights from the psychedelic experience, and how these can be 'integrated' into their life.[21] Clinical trials suggest this self-reflection helps the patient to understand the causes of their mental health condition, resulting in long-lasting benefits.[21,22] Some PAT clinical trial participants have reported feeling more self-reflective, motivated, and having "capacity for change".[23–25] Others report ongoing difficulties and require further support.[26] Some patients repeat the PAT treatment.[27]

Researchers emphasise the importance of therapeutic care for the patient before, during and after the psychedelic experience.[17] Clinical trials have shown that PAT may lead to "deeply meaningful, personally transformative experiences"[20] that can allow patients to engage with thoughts they had previously avoided, underlying issues and traumatic memories.[28]

1.2 Evidence for PAT efficacy

The evidence for the efficacy of PAT in treating specific mental health conditions is complicated.[6] When randomised controlled trials involve small numbers of participants, it is more difficult to say whether the results are generalisable. However, pooled analyses of these trials show that PAT can be more effective than commonly prescribed medications.[d,27]

[d] POST has published information about how randomised controlled trials and meta-analyses are conducted.

The trials carried out so far are described in a series of rapid evidence reviews published by POST in 2023 and 2024 and summarised in table 1.

Table 1: Main findings from PAT research

Depressive disorders (RR09)	Research has focused on PAT with psilocybin or ketamine. Most studies show a positive effect on symptoms, and effects can persist for several months after treatment.[13,29]
Anxiety disorders (RR10)	Small, randomised controlled trials involving between 12 and 51 participants show that PAT can be as effective as existing treatments in reducing anxiety symptoms. This effect can be sustained for months.[30,31]
Eating disorders (RR12)	Evidence is mostly from individual case studies.[32] A trial of 10 participants showed that PAT resulted in significant improvements in symptoms three months after a single session.[33] Further trials are taking place.[34]
Post-traumatic stress disorder (PTSD) (RR13)	Phase 3 randomised controlled trials investigating PAT using MDMA have found that participants in the treatment group improved significantly more than participants in the placebo group. One PTSD study involved 104 participants from the USA and Israel.[35] Another had 90 participants from the USA, Canada, and Israel.[35] In 2024, the US Food and Drug Administration (FDA) rejected an application to approve MDMA-assisted therapy as a treatment for PTSD, requesting an additional phase 3 trial.[36] Soon after, three PAT research papers detailing a phase 2 clinical trial relating to the application were retracted due to ethical concerns.[e] [37]
Addiction (RR16)	Two randomised controlled trials with over 90 participants each showed that PAT can treat alcohol dependence.[38,39] A trial with 15 participants showed that PAT can help with quitting smoking.[40]

1.3 Challenges in PAT research

Possession of controlled psychedelic drugs is illegal in the UK.[41] Use in research and medicine is tightly regulated through controlled drug legislation (see section 4).[42]

Controlled drugs are substances listed in the Misuse of Drugs Act 1971.[41] Their production, import, export, supply, possession and use are regulated by legislation.[41]

[e] The FDA decision and the journal retraction occurred after POST's rapid response was published. The ethical concerns are outlined in further detail on page 22.

Researchers in universities and hospitals require a Home Office licence to procure, store, and administer schedule 1 psychedelic drugs in PAT clinical trials.[f] [7] This makes PAT research time-consuming, expensive, and logistically difficult.[3,43]

Costs, logistical challenges and stigma have limited research to a small number of clinical trials with small numbers of participants.[3,18,44,45] Most studies are non-commercial and are funded through government grants and philanthropy.[46]

To understand safety and efficacy more accurately, PAT needs to be investigated with larger and longer clinical trials.[3,6,47,48]

Proposals to facilitate research

Academic researchers,[3,49] mental health charities,[50] some MPs[51,52], and patients[51] have suggested that psychedelic drugs should be rescheduled (moved from schedule 1 to schedule 2 of the Misuse of Drugs Regulations 2001) because of recent evidence suggesting their medicinal value.

This would remove some of the barriers to PAT clinical trials, while maintaining strict controls on their medical use and their legal status as class A drugs.

Researchers argue this would allow more phase 3 randomised controlled clinical trials to take place.[3] Phase 3 trials compare a new treatment with either a placebo, or the current best available treatment, to minimise the risk of bias. They are designed to measure effectiveness and to thoroughly assess risks and side effects.[53]

Phase 3 trials in psychiatry usually involve between 500 and 1,000 participants, have long follow-up periods (to measure the effects over time)[54] and are significantly more expensive to conduct than phase 2 trials.[55]

Policymakers[52,56] have stated that "legitimate research" with psychedelic drugs must be balanced with efforts to ensure there is no:

- diversion: illegal distribution of controlled drugs from medical settings
- misuse: non-medical use of controlled drugs that may cause harm

Many stakeholders are interested in PAT research, including academics,[57] campaigners[58] and biotechnology entrepreneurs.[59]

This topic can be controversial, and there are a wide range of opinions. For example, some wish to see more clinical trials,[57] and others are campaigning

[f] Ketamine is a psychedelic drug in schedule 2 of the Misuse of Drugs Regulations 2001 as it has a recognised medicinal use as a licensed analgesic (painkiller) and anaesthetic. Other psychedelic drugs are in schedule 1 due to a lack of recognised medicinal use (see section 4.2).

for psychedelic drugs to be available on prescription,[60] decriminalised[61] or legalised.[g] [63]

Divisive public opinion, and a lack of evidence from large clinical trials, can make the discourse challenging to understand.[18,64,65]

A Home Affairs Committee report published in August 2023 recommended "urgent" rescheduling of psychedelic drugs to enable larger clinical trials to take place, to better understand the safety and efficacy of PAT.

The government responded by commissioning the Advisory Council on the Misuse of Drugs (ACMD) to consider "barriers to research". In December 2023, the ACMD published a report which evaluated ways to make research with schedule 1 drugs, including PAT clinical trials, easier to conduct.[66]

The ACMD report did not make recommendations. It considered ways to "reduce barriers to research" and outlined potential implications.

For example, the report considered how research in universities and hospitals using schedule 1 drugs could occur without the need for a Home Office licence. This option considered how research could be conducted in accordance with schedule 2 drug requirements. The report suggested that this option would likely benefit researchers, but not industry. The report stated that "the ACMD does not consider there to be an increased risk of diversion" with this option.[66]

As of February 2025, the government is yet to respond to the ACMD report.

[g] Decriminalisation is when an activity remains illegal, but a person is not prosecuted if caught.[62] Decriminalisation is different to legalisation, which is when all penalties associated with an activity are removed.[62] Regulated use of psychedelic drugs in PAT clinical trials is not an example of decriminalisation nor legalisation.

2 Benefits and risks of psychedelic-assisted therapy

The benefits and risks of psychedelic-assisted therapy (PAT) need to be compared with the benefits and risks of conventional treatments.

Mental health conditions currently being investigated in PAT clinical trials are usually treated with daily doses of antidepressant drugs to manage symptoms (such as low mood).[67] A commonly used class of drug is selective serotonin reuptake inhibitors (SSRIs).[68] Patients may also receive therapy.[68]

These conventional treatments have been studied over longer periods of time, and with larger sample sizes, than PAT.[69] Evidence for their benefits and risks is therefore more robust.

There are some limitations to interpreting PAT benefits and risks:

- Benefits and risks of PAT are incompletely understood due to the small number and size of some clinical trials, and lack of long-term data.[6,47,48]
- Results of clinical trials for PAT using certain psychedelic drugs to treat certain mental health conditions cannot be generalised to other psychedelic drugs and other mental health conditions.[25]
- PAT involves giving screened clinical trial participants controlled doses of pure psychedelic drugs under medical supervision, and benefits and risks should not be directly compared with those for recreational use of psychedelic drugs.[65,70]

There are well-documented physiological and psychological risks when psychedelic drugs are used recreationally.[26] Many of these risks are mitigated when psychedelic drugs are administered in clinical settings.[h] [17,71]

Evidence suggests that the safety profile of some psychedelic drugs administered in PAT is better than some of the medications currently used to treat mental health conditions.[35] For example, a study comparing escitalopram (an SSRI) and psilocybin found that more side effects were experienced by the group taking escitalopram.[72]

[h] For example, potential risks associated with illegal psychedelic drug use in recreational settings (such as traffic accidents and toxic drug impurities) are absent from PAT, as it takes place in a controlled clinical environment and uses clinical-grade psychedelic drugs.

2.1 Immediacy and duration of therapeutic effects

PAT can lead to immediate and sustained benefits for some patients,[73,74] with some reporting being cured of chronic mental health conditions after treatment.[75]

For example, in a PAT clinical trial investigating psilocybin in the treatment of depression, none of the 24 participants required daily antidepressant treatment for the four weeks following the psychedelic experience.[22] Two thirds of the participants were not taking daily antidepressant treatment a year later. [22]

Response and relapse rates for depression vary depending on the type of treatment.[i] Patients may try several types of medication, therapy, or a combination of both before seeing results.[75] If treatments do not relieve a patient's symptoms, they are said to have treatment-resistant depression.[j] [77,78]

Some patients with treatment-resistant depression get better after PAT.[79,80] Research suggests this might be because the psychedelic experience enables patients to think about their mental health problems in a different way during therapy.[15]

Some antidepressants may decrease some of the effects of psychedelic drugs.[81,81,82] PAT patients may need to stop using antidepressants before undergoing PAT.[83] This requires patients to understand risks of:

- common antidepressant withdrawal symptoms[84,85]
- symptoms potentially worsening because they are not taking medication[85]

2.2 Physiological side effects

PAT patients often experience short-term side effects, including anxiety, nausea, blurred vision, dizziness and headaches.[86,87] These do not usually last longer than the duration of the psychedelic experience, as the body rapidly processes and excretes psychedelic drugs.[70] Some patients report headaches that persist for a day after the treatment.[20,72]

[i] Response rates refer to the proportion of patients that get better during treatment. Relapse rates refer to the proportion of patients whose symptoms worsen either during or after treatment.

[j] Definitions of treatment-resistant depression vary.[76] Most definitions refer to situations where a patient's symptoms do not improve after 'adequate' antidepressant treatments, such as two courses of antidepressants.[76]

Some patients experience a short-term rise in heart rate and/or blood pressure during a psychedelic experience.[88] Patients with certain heart conditions are excluded from PAT clinical trials to limit risk (box 1).[15]

The toxicity of psychedelic drugs is low. For example, the lethal dose of psilocybin is estimated to be 1,000 times greater than the dose currently administered during PAT.[20] The dose of ketamine administered in PAT clinical trials is approximately 10 times less than the dose of ketamine commonly used in anaesthesia.[89,90]

2.3 Psychological side effects

During PAT, patients report vivid thoughts, dream-like states, and overwhelming feelings.[91] Patients with post-traumatic stress disorder (PTSD) may have 'flashbacks' during the psychedelic experience.[92]

Some patients find these thoughts to be distressing in the moment, but can report finding the experience valuable during the 'integration' phase of PAT (box 1).[93]

The intensity of the experience may induce anxiety.[18] In one study, 11 of the 36 participants (who had undergone extensive screening) experienced a period of significant fear.[94] This did not persist after the psychedelic experience.[94]

The likelihood of distressing experiences depends on context.[95] They are less likely to occur when a patient is relaxed and comfortable.[17]

Therapists who support the patient before, during and after the psychedelic experience are specifically trained in PAT. This support can minimise distress and the occurrence of negative experiences.[17]

If patients experience extreme distress during a psychedelic experience, a single dose of medicine (such as a benzodiazepine) can quickly stop psychological effects.[17]

Outside clinical trial settings, surveys have been used to understand the experiences of people who use psychedelic drugs recreationally. Some report psychological difficulties, such as anxiety and 'flashbacks', lasting over a year.[26] Other surveys report that the majority of recreational users report positive experiences, with few side effects.[96]

2.4 Long-term effects

Research into the long-term psychological and physiological effects of PAT is limited.[74] Several studies have followed clinical trial participants for months and years after treatment. In one study, 24 participants were surveyed 14 months after their treatment. None reported adverse effects.[97]

2.5 Potential for dependence, addiction and abuse

Evidence suggests that psilocybin, DMT and LSD are unlikely to be addictive.[12,98,99] Unlike drugs such as cocaine they do not act on the brain's 'reward pathway', so people are unlikely to form a habit of using them.

However, other psychedelic drugs such as Ketamine[100] and MDMA[101] have addictive potential.

For some psychedelic drugs, such as psilocybin and LSD, physiological and psychological effects diminish with repeated use within a short timeframe. This means if someone takes the same drug twice within a few days the second dose produces less of an effect. This is called tolerance.[102] This tolerance means people are very unlikely to develop dependence or addiction to these drugs.[20]

PAT patients take psychedelic drugs in controlled settings in the presence of clinicians. This makes diversion and misuse of these drugs very unlikely.[3,65,103]

2.6 Treatment duration and impact on the patient

During PAT, patients must commit to preparation therapy before the psychedelic experience. The psychedelic experience takes a day to complete (box 1).[80] Patients are required to attend multiple integration therapy sessions after the psychedelic experience.[35] Some patients experience longer-term difficulties and require ongoing integration support from therapists.[104]

These time demands may be off-putting for some patients.[105]

Costs and time demands of PAT need to be considered over long time scales and compared with standard treatments, which may involve regular therapy, appointments and medication.[106,107] These costs and commitments are borne by the patient, staff and the clinical trial organiser or healthcare provider.

Some studies suggest that patients for whom PAT is successful:

- do not need to take remember to take daily medication
- will not experience the side effects of these medications
- may not need to attend therapy
- may be able to return to work[106]

PAT research is expensive and logistically challenging (see section 4).[43] If PAT treatment becomes available, it is likely to be expensive for healthcare providers in the short run but it may be cost-effective in the long run (see section 5).[108]

2.7 Comparison with conventional antidepressant treatment

Different antidepressants can be prescribed at different doses. The proportion of patients who see an improvement in their symptoms when taking antidepressants is highly variable.

Some patients feel the effects of antidepressants one to two weeks after starting treatment.[109,110] UK guidelines say that if a patient is going to feel the effects of an antidepressant medication at a certain dose, it "usually starts to work within four weeks".[111]

If symptoms do not improve after four weeks, or side effects are concerning, a patient may be prescribed a different antidepressant, or the same antidepressant at a different dose.[111]

Approximately one third of patients with depression respond to initial SSRI treatment. Of the two thirds of patients who do not respond to the initial treatment, approximately 30% respond to a different type of treatment.[112]

Antidepressants cause side effects, which are usually mild (such as nausea, anxiety and headaches), in half of patients.[113] Rare side effects include heart problems and suicidal thoughts.[113,114]

As antidepressants are taken daily for months or years, side effects can affect quality of life over long periods of time.[18,115] Most patients find that side effects improve over time.[116]

Approximately half of PTSD patients respond to SSRI treatment, but some never recover fully.[117]

3 Pathway from research to treatment

In the UK, several organisations are involved in medicine becoming available to patients. There are several stages a medicine must go through:

1. Researchers submit information about planned clinical trials to the Health Research Authority (HRA).
2. Applications are reviewed by the:
    a. Medicines and Healthcare products Regulatory Agency (MHRA), which regulates medicines in the UK[118]
    b. Research Ethics Committee, which ensures clinical trial design minimises risk and safeguards participant welfare[119]
3. If approved, researchers conduct clinical trials and publish results.
4. If the results of these trials demonstrate sufficient safety and efficacy, manufacturers can apply for marketing authorisation for the medicine from the MHRA,[120] which assesses safety and efficacy.[121]
5. If the MHRA grants marketing authorisation, the medicine has a product licence. If the authorised medicine is a controlled drug, the MHRA invites the Advisory Council on the Misuse of Drugs (ACMD) to investigate if rescheduling is necessary.[66] The product licence:
    a. allows pharmaceutical companies to bring a drug to market in the UK[k]
    b. states which medical conditions the drug is licenced to treat[l]
    c. outlines safe use, such as dosage and frequency of dosing[125]
6. Manufacturers with a product licence can request that the medicine is assessed by the National Institute for Health and Care Excellence

[k] A product licence allows a drug to be prescribed or sold in the UK.[122] It does not mean the drug will be used by the NHS and it does not in itself make a drug available on prescription. Unlicensed medicines can be prescribed in "exceptional"[123] circumstances if professional guidelines are followed, and the patient gives informed consent.[124]

[l] 'Off-label' refers to the use of licensed medicines for medical conditions they are not licensed to treat. For example, ketamine is a licensed anaesthetic and analgesic. It is used off-label to treat mental health conditions.

(NICE) to determine if it is a clinically effective and cost-effective treatment.[m] [126]

7. If NICE approves the medicine, it can be made available to relevant groups of patients via the NHS.

In the UK, as of February 2025, PAT (with the exception of ketamine[127]) is mostly being investigated in phase 2 clinical trials. Some phase 3 PAT clinical trials are recruiting patients in the UK.[128]

[m] The assessment process differs slightly in Scotland, Wales, and Northern Ireland.

4 Psychedelic-assisted therapy clinical trials: Regulatory challenges

In the UK, controlled drugs are categorised into both classes (table 2) and schedules (table 3):

- Classes determine penalties associated with possession and supply.
- Schedules determine lawful use in research and medicine.

A drug's schedule is independent of its class.[n] Reclassification and rescheduling are different legal processes.

All psychedelic drugs, except ketamine, are in class A and schedule 1.[129]

Researchers and policymakers have expressed concerns that circular arguments hamper advances in clinical research, meaning potentially valuable medicines are perpetually 'stuck' in schedule 1.[3]

In March 2023, the Minister for Crime, Policing and Fire said "there is an element of chicken and egg or Catch-22 about the situation, because we need to do the research before there is an evidence base to justify the rescheduling that might be merited".[130]

4.1 Controlled drug classes and the Misuse of Drugs Act 1971

The production, supply, possession, and use of controlled drugs outside of clinical settings is regulated under the Misuse of Drugs Act 1971.[41] Drugs considered to be most harmful when misused are in class A and carry the greatest penalties.[131]

[n] For example, ketamine is in class B and schedule 2, whereas heroin is in class A and schedule 2. This means both are approved for use in medicine, but penalties for recreational use of heroin are more severe than for ketamine.

Table 2: UK controlled drug classes

Class	Penalties	Examples	
		Controlled drugs used in PAT	**Other controlled drugs**
A	Up to seven years in prison, an unlimited fine or both for possession Up to a life sentence in prison, an unlimited fine or both for supply	MDMA, known as ecstasy LSD Psilocybin found in 'magic mushrooms' DMT	Cocaine Heroin
B	Up to five years in prison, an unlimited fine or both for possession Up to 14 years in prison, an unlimited fine or both for supply	Ketamine	Amphetamines Cannabis
C	Up to two years in prison, an unlimited fine or both for possession Up to 14 years in prison, an unlimited fine or both for supply		Nitrous oxide, known as laughing gas Benzodiazepines, a group of sedative medicines

Source: Gov.uk, Drugs penalties

4.2 Controlled drug schedules and the Misuse of Drugs Regulations 2001

The Misuse of Drugs Regulations 2001 regulates the legitimate use of controlled drugs and groups them into schedules 1 to 5.[132] The schedule of a drug reflects its use in medicine[133] and its harms when misused.[o]

The government stated that controlled drugs in schedule 1 have "no recognised medicinal use" in the UK and thus have the greatest restrictions on research.[135]

Controlled drugs with recognised medical uses are in schedules 2 to 5. Controlled drugs with more potential for harm and misuse are in schedules with stronger safeguards (table 3).

The ACMD has stated that being in schedule 1 "does not mean the drug is any more harmful than controlled drugs in Schedule 2".[66]

Academic researchers,[3,49] mental health charities,[50] some MPs[51,52] and patients[51] have argued that some evidence showed the potential medicinal value of psychedelic drugs, and that therefore their schedule 1 status is no longer appropriate.

Table 3: UK drug schedules

Schedule	Use in medicine	Examples	
		Controlled drugs used in PAT	**Other controlled drugs**
1	No recognised medical use in the UK. Use in research requires: • a controlled drug licence[p] from the UK Home Office, and inspection visits • secure storage facilities	• LSD • Psilocybin, found in 'magic mushrooms' • MDMA, known as ecstasy • DMT and 5-MeO-DMT	• Raw opium • Cannabis

[o] The Advisory Council on the Misuse of Drugs (ACMD) has referred to "perceived risk of misuse".[66] The UK Government has referred to "potential harms when misused".[134]

[p] A controlled drug licence allows companies and organisations in England, Wales, Scotland and Northern Ireland to possess, manufacture, produce or supply controlled drugs.[136]

	• enhanced Disclosure and Barring Service (DBS) checks for researchers and clinicians • records to be kept in a controlled drug register[q]		
2	Used in medicine. Can be prescribed (if marketing authorisation has been sought and approved), lawfully possessed and supplied by doctors and pharmacists. A controlled drug licence is required (with exceptions for research in universities and hospitals). Use must be recorded in a controlled drug register (with some exceptions).	• Ketamine	• Heroin (diamorphine) • Morphine • Cocaine • Amphetamine • Most cannabis-based products for medicinal use (CBPMs)
3	Used in medicine. Use is subject to special prescription requirements. Safe custody requirements apply, with some exceptions. A controlled drug licence is required (with exceptions for research in universities and hospitals). Use does not need to be recorded in a controlled drug register.		• Tramadol, an opiate painkiller • Barbiturates, a group of sedative medicines • Temazepam, a benzodiazepine to treat insomnia
4	Used in medicine. Use is not subject to safe custody requirements. Controlled drug prescription requirements do not apply. A controlled drug licence is required (with exceptions for research in universities and hospitals). Use does not usually need to be recorded in a controlled drug register.		• Sativex®, a CBMP • Sedative medicines, including benzodiazepines and non-benzodiazepine hypnotics

[q] Controlled drug registers aim to prevent diversion and misuse. They are documents listing amounts of controlled drugs received from manufacturers and administered in clinical trials.[137]

5	Used in medicine. A controlled drug licence is required (with exceptions for research in universities and hospitals).	• Highly diluted preparations of morphine and codeine (opiate painkillers)

Source: British National Formulary, Controlled drugs and drug dependence and ACMD, Correspondence to the Minister for Crime, Policing and Fire on barriers to reasearch (PDF), 22 December 2023

4.3 Costs associated with PAT clinical trials

Researchers have stated that aspects of PAT research make it expensive (table 4).[3,43]

Table 4: Costs associated with PAT clinical trials

Cost	Explanation

Compliance with controlled drugs regulation	• Fees associated with the annual Home Office domestic licence include:
	  • licence application fees of £3,000 to £4,000[138]
	  • annual renewal fees of £300[138]
	  • inspection fees for study locations, each costing £300 to £1,400[138]
	  • DBS check fees for all staff handling psychedelic drugs listed in the controlled drug register[136]
	• Separate licences are required for each stage of the supply chain, including manufacture.[66,139]
	• Export and import licences are required if psychedelic drugs are synthesised abroad.[138]

Acquiring 'clinically approved' psychedelic drugs[r]	• Psychedelic drugs are synthesised by only a small number of chemical manufacturers, and costs can be prohibitively high.[3] • Manufacturers synthesising psychedelic drugs require licences and secure transportation and storage facilities.[66,140]

[r] Clinically approved drugs are pure substances suitable for human use.

Building requirements	• Schedule 1 drugs must be stored in a lockable fridge-freezer bolted to the floor and wall in a designated room with controlled entry and CCTV surveillance.[66,141]
Staff time	• Staff must submit detailed licence applications and manage licence requirements.[43,66] • Clinical staff, such as psychotherapists, prepare PAT patients, supervise the patients' psychedelic experience, and provide support during integration (box 1).

4.4 Incompatible licence and funding timescales

Researchers highlighted that elements of PAT clinical trials have incompatible timescales:[66]

- Research grants are usually awarded for a fixed period (for example, one to three years).[70]
- Obtaining a controlled drug licence for each study location takes approximately one year.[3]
- Obtaining export and import licences is time-consuming.[70]

Researchers reported that:

- Some funding decisions depended on having obtained a Home Office licence. There have been instances where funding deadlines have passed before licence decisions were made.[57,70]
- Delays in psychedelic drug synthesis can lead to export and import licences (valid for three months) expiring.[142]

4.5 Challenges with academic collaboration

Researchers highlighted that the "burden" associated with working with schedule 1 drugs is a deterrent, which limits the number and diversity of academics in the field.[3,43,65,70,140]

Researchers explained that export and import licences, and individual licences for each location in the study, made collaboration challenging.[3]

Domestic and international collaboration is more likely in phase 3 clinical trials.[s]

Researchers also cited the stigma associated with psychedelic drugs as a barrier to research (see section 6.1).

[s] Phase 3 trials involve between 500 and 1,000 participants who have the medical condition being studied. Recruitment from multiple locations is therefore usually necessary. Having clinical trial participants from different locations also helps to reduce sample bias.

5 Policy considerations for clinical trials and treatment

PAT is not available in the UK as a treatment outside of regulated clinical trials, except for ketamine-assisted therapy.[t]

5.1 Safeguarding guidance for clinical trials

Patients with mental health conditions can feel vulnerable during PAT, especially during the psychedelic experience.[18,144]

Some participants in Canada have alleged that they experienced misconduct during PAT clinical trials led by the Multidisciplinary Association for Psychedelic Studies (MAPS).[u]

Researchers have developed safeguarding guidance to minimise risks to participants, such as having two trained "monitors" present during the psychedelic experience and filming the session.[17,149]

5.2 Preventing drug diversion and misuse

In clinical trials, PAT participants take psychedelic drugs in clinical settings and in the presence of a clinician.[65] Participants cannot take drugs home.[65]

There are controlled drug registers and surveillance to deter researchers from removing psychedelic drugs from universities and hospitals.[150]

The ACMD has stated that it does not consider there to be an increased risk of diversion from PAT clinical trials if psychedelic drugs are "subject to the

[t]Ketamine-assisted therapy is available in the UK in private clinics. It is not available on the NHS.[143]

[u]A phase 2 clinical trial by MAPS has been investigated after 2015 footage emerged showing a participant with PTSD experiencing distress during a psychedelic experience. The participant was restrained by the psychiatrist and unlicensed therapist present.[145] In 2018, the participant filed a claim stating that their treatment was "inappropriate, unprofessional, harmful".[146] In 2019, the Supreme Court of British Columbia reviewed the participant's lawsuit, which was later settled out of court.[147] In 2024, three research papers relating to this clinical trial were retracted by the journal Psychopharmacology due to "unethical conduct" and a "potential competing interest" not being declared.[148]

same restrictions and safeguards of existing Schedule 2 controlled drugs" (table 3).[66]

Research into psychedelic drugs in controlled settings in Germany has not resulted in increased diversion or misuse.[66]

5.3 Making psychedelic-assisted therapy available as a treatment

Stakeholders highlighted that if PAT treatments were to be offered privately or on the NHS, policymakers would need to consider how to:

- ensure equity of access[v] [65,153,154]
- minimise risks of diversion and misuse, if psychedelic drugs became more widely used in clinical settings[155]
- determine affordability in the short and long term[153]
- scale resource-intensive treatment[153]

- Policymakers would also have to consider whether availability of PAT through healthcare providers might increase illicit use (because of increased interest)[64,65,154,156] or decrease it (because of increased access to PAT)[157]

[v] Stakeholders highlighted possible equity of access parallels with cannabis-based products for medicinal use (CBPMs). In the UK, CBPMs are available on the NHS and privately. In January 2023, the NHS Business Service Authority released data showing that 89,239 prescriptions for CBPMs were issued between November 2018 and July 2022.[151] Fewer than five of these were NHS prescriptions.[152]

6 Psychedelic drugs: Public perception

6.1 Stigma and acceptance

In a 2021 YouGov poll, 1,763 UK adults were asked about the use of psilocybin in medical research:

- 55% were supportive
- 31% were unsure
- 13% were opposed[w] [158]

A 2021 UK survey of 12 PAT researchers reported that the class A status of most psychedelic drugs leads to assumptions about criminality and danger, affecting:

- access to research funding
- approval of clinical trials by university and hospital ethics committees
- willingness of universities and hospitals to host clinical trials or be involved in collaborative research, due to concerns that researchers might:
    - inadvertently break the law
    - incur financial penalties
    - incur reputational damage
- recruitment of clinical trial participants[x] [43]

[w] 58% supported changing the law to allow patients with terminal illness to access PAT. When survey participants were informed of the results of PAT clinical trials and how psychedelic drugs were being used by patients "suffering end of life distress" in Canada, 68% said they supported a change in the law.

[x] Patients taking SSRIs also report social stigma associated with antidepressant medications.[78]

6.2 Confusion surrounding rescheduling, reclassification, and prescription

Stakeholders highlighted widespread confusion between controlled drug classes and schedules.[64,159]

Stakeholders were also concerned that calls to reschedule some psychedelic drugs to facilitate more PAT research are conflated and confused with campaigns to:

- reschedule and licence some psychedelic drugs so they can be obtained by prescription
- reclassify some psychedelic drugs (that is, change their Class A status)
- decriminalise or legalise some psychedelic drugs[18,64]

6.3 Illegal use of psychedelic drugs

High-profile books, films and articles about PAT clinical trials are believed to have increased public interest in psychedelic drugs.[70,160,161]

Data on illegal drug use is hard to collect.[70,162] A 2023 Office for National Statistics survey asked people in England and Wales aged 16 to 59 about their "about use of drugs in the last year". The percentage of respondents who reported using LSD and 'magic mushrooms' had risen from 0.7% in 2020 to 1% in 2023.[163] This trend in the recreational use of psychedelic drugs is also seen in other countries.[y] [164]

Researchers highlighted how use of psychedelic drugs outside clinical settings requires access to accurate safety information (such as the safe dosage) to limit dangers.[154]

[y] The Global Drug Survey collected data from over half a million people between 2014 and 2020. During this time, the use of illegal drugs, including cannabis, amphetamines, and cocaine, has increased. The report highlighted a global increase in the use of psychedelic drugs, notably ketamine and 'magic mushrooms'.[164]

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POST is grateful to Dr Stephen Naulls, a Parliamentary Academic Fellow and NIHR-funded Academic Clinical Fellow from Brighton and Sussex Medical School, for his support in researching and writing this briefing.

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POST would like to thank interviewees and peer reviewers for kindly giving up their time during the preparation of this briefing, including:

- Home Office*
- Timothy Davis, Director of Psychedelic Policy and Regulation, Centre for Evidence Based Drug Policy
- Jules Evans, Director, the Challenging Psychedelic Experiences Project*
- Josh Hardman, founder, Psychedelic Alpha*
- Professor Joanna Neill, Professor of Psychopharmacology, University of Manchester*
- Professor David Nutt, Director of the Centre for Psychedelic Research, Professor of Neuropsychopharmacology, Imperial College London*
- Alex Piot, Director of Research, Centre for Evidence Based Drug Policy
- Professor W David Strain, University of Exeter Medical School and UK Parliament Thematic Research Lead for Health*
- Professor Sara Tai, Professor of Clinical Psychology, University of Manchester

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