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The Pros and Cons of Rescheduling Psilocybin

Summary

1. **Psilocybin is a naturally occurring substance that produces a window of neuroplasticity that lasts for a number of hours making it a powerful tool in the treatment of mental health conditions such as depression and addiction.**

2. **Psilocybin is consistently found to be one of the safest controlled drugs, is physiologically non-toxic and does not form dependence.**

3. **Psilocybin's status as Schedule 1 under the Misuse of Drugs Regulations 2001 increases the cost, duration and stigma associated with undertaking research and blocks the ability of psychiatrists to use their discretion and expertise to decide whether to prescribe it to patients.**

4. **Psilocybin's current status as a Schedule 1 controlled drug is incommensurate with the evidence of its harm and utility, yet no review of the evidence has ever been conducted by the Home Office. Psilocybin was controlled in 1971 because no applications had yet been made for it to be used as a medicine; its current scheduling is an accident of history as opposed to evidential.**

5. **Psychiatrists in Australia, Canada and some US states are already able to use their expertise and discretion to prescribe psilocybin to patients who may benefit ahead of a product containing it reaching market authorisation.**

6. **Yougov nationally representative polling shows that 68% of the public were in support of legislative change that would facilitate patient access to psilocybin when they learnt that it was already available in Canada, with only 9% opposed.**

7. **The Royal College of Psychiatrists and many mental health charities including CALM and SANE are in support of rescheduling psilocybin.**

8. **The Home Office has the legal power to commission an urgent review of the evidence of psilocybin's harms and utility with a view to rescheduling with or without the request coming from the DHSC.**

9. **Rescheduling psilocybin would:**
    a. Correct an historical 50 year old error by which psilocybin is tightly controlled by the Home Office without legitimate reason.
    b. Facilitate research ahead of the implementation of recommendations from the yet to published ACMD report into barriers to research.
    c. Facilitate data collection in the real world, supporting the MHRA and NICE approval processes.
    d. Allow for medical professionals to make their own decisions on whether or not prescribe the drug as a special without government restriction, as is already possible with drugs not within Schedule 1.
    e. Remove Home Office impediments on an issue concerning the DHSC and medical colleges.

10. **Rescheduling psilocybin would not:**
    a. Increase illegitimate or irresponsible use or increase diversion.
    b. Change criminal penalties on the possession and supply of psilocybin by changing its Class A status under the Misuse of Drugs Act 1971.
    c. Disincentivise companies from developing medical products containing psilocybin for market and taking them through the normal MHRA approvals process.

11. **Conclusion - The Home Office should commission an urgent ACMD review of the evidence of the relative harms and utility of psilocybin with a view to rescheduling at the earliest opportunity.**

Annex 1 - Clinical Trials with Psilocybin - Completed and Ongoing (2006 - 24/05/2023)

Annex 2 - Public Attitudes to Psilocybin report summary by Psilonautica and DrugScience

Annex 3 - Open letter of Support signed by the Royal College Psychiatrists, CALM, SANE and others.

1. **Psilocybin is a naturally occurring substance that produces a window of neuroplasticity that lasts for a number of hours making it a powerful tool in the treatment of mental health conditions such as depression and addiction.**

- A single dose administered in a supportive environment has been found to
    - have a rapid and enduring reduction in depression symptoms for up to 12 weeks[1].
    - be as effective as the leading antidepressant over a period of six months[2].
    - help 80% of heavy (30+ a day) smokers remain abstinent for over six months[3].

[1]Goodwin, G.M. *et al.* (2022) "Single-dose psilocybin for a treatment-resistant episode of Major Depression," *New England Journal of Medicine*, 387(18), pp. 1637–1648. Available at: https://doi.org/10.1056/nejmoa2206443.
[2]Carhart-Harris, R. *et al.* (2021) "Trial of psilocybin versus escitalopram for depression," *New England Journal of Medicine*, 384(15), pp. 1402–1411. Available at: https://doi.org/10.1056/nejmoa2032994.
[3]Johnson, M.W., Garcia-Romeu, A. and Griffiths, R.R. (2016) "Long-term follow-up of psilocybin-facilitated smoking cessation," *The American Journal of Drug and Alcohol Abuse*, 43(1), pp. 55–60. Available at: https://doi.org/10.3109/00952990.2016.1170135.

- Depression is the leading cause of suicide and on average 125 people in the UK take their own lives each week. Mental health costs the UK £117.9 bn/year (5% of GDP)[4]. Psilocybin assisted therapy relieves symptoms without the use of daily medication, risk of dependency on said medications, and shows potential for treatment resistant depression and other disorders such as anxiety or addictions. The economic savings and quality of life improvement could be immense.
- A list of completed and ongoing clinical trials can be found in Annex 1.

2. **Psilocybin is consistently found to be one of the safest controlled drugs, is physiologically non-toxic and does not form dependence.**
   - **Risks are further mitigated within supportive psychotherapeutic environments[5]**. Contary to popular fears around these drugs, a review of the 20 years of psychedelic therapy research in the UK prior to 1971 found that out of 4000 patients, totalling 50,000 doses, there were only two completed suicides and thirty-seven patients with a prolonged negative reaction (>0.1%)[6].
   - **Psilocybin is proven to not foster dependence. It addresses the causes of mental ill health,** rather than treating symptoms through emotional blunting with SSRI antidepressants upon which patients can come to rely for decades, opening routes to cure rather than simply symptom management. A patient on psilocybin trials in the UK said *"My previous treatments, talking therapy and meds, were next to useless, utterly useless. My experience of psilocybin has been very positive*"[7].

3. **Psilocybin's status as Schedule 1 under the Misuse of Drugs Regulations 2001 increases the cost, duration and stigma associated with undertaking research and blocks the ability of psychiatrists to use their discretion and expertise to decide whether to prescribe it outside of clinical trials as a special ahead of market authorisation.**
   - Schedule 1 imposes barriers of increased cost, duration and stigma which seriously hinders neuroscientific and clinical research through the requirements on researchers to hold multiple costly Home Office licences[8].
   - **While research into Schedule 1 drugs is possible, only a tiny fraction of the possible research actually takes place,** almost all of which is conducted by large pharmaceutical companies trying to bring drugs to market. This red tape not only artificially discourages competition as only very big companies can afford to conduct the research. It also means that as the research is unnecessarily more expensive, it will be the taxpayer who ultimately picks up the bill through higher drug prices for the NHS[9].
   - **The ACMD are currently undertaking a review of the barriers to research into 'controlled drugs beyond cannabinoids'.** However there is no published completion date. It was in 2017 that the Government first

[4] Mcdaid, D., Park, A.-L., Wilson, N., Davidson, G. & John, A. The economic case for investing in the prevention of mental health conditions in the UK.
https://www.mentalhealth.org.uk/sites/default/files/2022-06/MHF-Investing-in-Prevention-Report-Summary.pdf.
[5]Carhart-Harris, R. L. *et al.* Psychedelics and the essential importance of context. *J. Psychopharmacol.* 32, 725–731 (2018).
[6]Malleson, N. Acute adverse reactions to LSD in clinical and experimental use in the United Kingdom. *Br. J. Psychiatry* 118, 229–230 (1971).
[7]Watts, R., Day, C., Krzanowski, J., Nutt, D. & Carhart-Harris, R. Patients' accounts of increased 'connectedness' and 'acceptance' after psilocybin for treatment-resistant depression. *J. Humanist. Psychol.* 57, 520–564 (2017).
[8]Howard A, Neill JC, Schlag AK, Lennox C. Schedule 1 barriers to research in the UK: An in-depth qualitative analysis. *Drug Science, Policy and Law*. 2021;7. doi:10.1177/20503245211049313
[9] Rucker J, Schnall J, D'Hotman D, et al. (2020) Medicinal use of psilocybin: reducing restrictions on research and treatment. Report by CDPRG and the Adam Smith Institute, https://www.cdprg.co.uk/psilocybin.

asked the ACMD to review this, over 6 years ago[10]. The Government then rejected the AMCD's long term recommendations.

- In 2016 then Home Secretary Amber Rudd first commissioned the ACMD to investigate these barriers. The ACMD was first commissioned to conduct part 2 of their Review of Barriers to Research on Controlled Drugs Beyond Synthetic Cannabinoid Receptor Agonists in March 2021, and again in December 2022, and for a third time in June 2023. Meanwhile UK industry and patients are falling behind.
- **The ACMD's report will not review the evidence for psilocybin's schedule 1 status**, leaving a 50 year injustice unaddressed and patients without access.
- **Removal of barriers to research will not allow for psychiatrists to use their discretion and expertise in prescribing the psilocybin as a 'special'** if they so choose as they are currently able to do with other controlled drugs that are not in Schedule 1.
- **The announcement that psychedelics will benefit from expedited approvals of medicines via the MHRA announced in the budget would still leave UK patients without access** until approval has been achieved abroad, leaving the UK trailing behind Canada, Australia and some US states. In this scenario the UK is a world bio-science follower and not leader. Leading UK academics have had to relocate to North America and Australia where the research and prescription is easier, leading to a brain drain[11][12].

4. **<u>Psilocybin's current status as a Schedule 1 controlled drug is incommensurate with the evidence of its harm and utility yet no review of the evidence has ever been conducted by the Home Office since it was first controlled in 1971. Psilocybin was only controlled so harshly at the time because no applications had yet been made for it to be used as a medicine; its current scheduling is an accident of history.</u>**
   - There is no evidential basis for psilocybin's current status as a Schedule 1 substance, and there never has been[13]. The Government has confirmed it has no evidence of harms of psilocybin in various recent Written Parliamentary Questions[14].
   - In 1971 when the Misuse of Drugs Act was instituted, no applications for market authorisation of psilocybin containing medicines had been received by the UK's Health and Medicines Regulatory Agency (MHRA). Drugs with historical use within medicine but with a higher abuse potential than psilocybin thus found themselves less stringently controlled. Over fifty years on, cocaine and heroin remain less tightly controlled than psilocybin.

5. **<u>Psychiatrists in Australia, Canada and some US states are already able to use their expertise and discretion to prescribe psilocybin to patients who may benefit ahead of market authorisation.</u>**

[10]Iversen, L. & Ali, M. Scheduling under the Misuse of Drugs Regulations 2001 and its impact upon research. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/578782/MDR-2001-Scheduling-and-its-impact-upon-research.pdf.
[11]Robin Carhart-Harris • UCSF Profiles. https://profiles.ucsf.edu/robin.carhart-harris.
[12]Dr Ben Sessa MBBS (MD) BSc MRCPsych. Ben Sessa Moves to Australia to work on MDMA trials. *Twitter* https://twitter.com/BenSessa/status/1647886713786626049?cxt=HHwWgsCz1YePvN4tAAAA (2023).
[13]WPQ Evidential Basis for Psilocybin in Schedule 1. https://questions-statements.parliament.uk/written-questions/detail/2021-05-26/7725.
[14] WPQ Psilocybin Harms. *TheyWorkForYou* https://www.theyworkforyou.com/wrans/?id=2023-02-17.146749.h&s=psilocybin.

- In February 2023 the Australian TGA rescheduled psilocybin and MDMA[15], allowing licensed psychiatrists to prescribe them for the treatment of depression and PTSD respectively from July.
- In 2018 the United States' FDA already granted psilocybin and MDMA Breakthrough Therapy status for depression and PTSD respectively, fast tracking them through the process to medical access, meaning they could both reach market authorisation by 2025. States including Oregon and Colorado have legalised access to professionally guided psilocybin sessions for adults over the age of 21.
- In January 2002 Canada psychiatrists became able to prescribe psilocybin to patients for end of life distress related to terminal cancer diagnoses and post traumatic illness through their Special Access Program ahead of market authorisation - patients have already begun to receive prescribed access.

6. **Yougov nationally representative polling shows that 68% of the public were in support of legislative change that would facilitate patient access to psilocybin when they learnt that it was already available in Canada, with only 9% opposed.**
   - There is increasing public support and demand for facilitating research and patient access to psilocybin as demonstrated by positive mainstream media attention across the spectrum of publications, from the Daily Mail to the British Medical Journal[16].
   - Details of the nationally representative sample can be found in Annex 2.

7. **The Royal College of Psychiatrists and many mental health charities including CALM and SANE are in support of rescheduling psilocybin.**
   - **If psilocybin treated a physical health condition like cancer, government inertia to not swiftly lift barriers into research and treatment with this level of clinical potential and safety profile would be much criticised.** This is an example that despite the ongoing mental health crisis and opportunity, parity of mental and physical health is still unachieved, and UK patients wait without relief for safe and effective medicines.
   - **The scheduling of psilocybin is a health issue but the Home Office is blocking the ability of psychiatrists to prescribe psilocybin at their own discretion as they can with other less controlled drugs, regardless of whether they have yet reached market authorisation, without reason.**
   - A letter signed by the Royal College Psychiatrists, CALM, SANE and others can be found in Annex 3.

8. **The Home Office has the legal power to commission an urgent review of the evidence of psilocybin's harms and utility with a view to rescheduling without or without the request coming from the DHSC.**
   - **There are three routes to rescheduling**;

     1) A medical product containing psilocybin reaches market authorisation by MHRA triggering an ACMD review of the scheduling of that product rather than the generic compound (as was the case with Sativex in 2018). This would leave the generic molecule in Schedule 1, perpetuating a 50 year injustice. While it is likely a product will reach this stage in 2025 patients are demanding access now and psilocybin's Schedule 1 status blocks the ability of psychiatrists to prescribe at their own discretion.

[15]Change to classification of psilocybin and MDMA to enable prescribing by authorised psychiatrists. *Therapeutic Goods Administration (TGA)*
https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists (2023).
[16]King LA, Nutt DJ, Nichols DE. Remove barriers to clinical research for schedule 1 drugs with therapeutic potential. BMJ. 2023;381:p981. doi:10.1136/bmj.p981

2) The ACMD could self-commission a review of the evidence. This is unlikely to happen due to the constraints upon the ability of the ACMD to self commission.

3) The Home Office can commission an ACMD review of the evidence and there is precedent to commission such a review with Cannabis Based Products for Medicinal Use (CBPM). The Home Office can either be requested to commission such a review by the DHSC or can take it upon themselves to get out of the way of a health issue and stop blocking the prescription of psilocybin at the discretion of medical professionals and their colleges.

9. Rescheduling psilocybin would:

a) Correct an historical 50 year old error by which psilocybin is tightly controlled by the Home Office without legitimate reason.

In 1971 psilocybin was controlled by the Misuse of Drugs Act because the MHRA was yet to receive an application for its use as a medicine, whereas heroin and cocaine which had use in medicine, but a much higher abuse potential, were less stringently controlled. Fifty years on this remains the case despite overwhelming evidence that psilocybin is relatively non toxic and has a definite utility within medicine. The original scheduling of psilocybin was an accident of history that could easily be corrected, yet no review of the evidence has ever been conducted.

b) Facilitate research ahead of the implementation of recommendations from the yet to published ACMD report into barriers to research.

Part two of the ACMD's report into barriers to research will produce recommendations which when implemented should facilitate research into more substances than just psilocybin, and this is welcomed. An urgent review of the evidence of psilocybin with a view to rescheduling would rapidly lift barriers to research into this substance which should not have been there in the first place and would unlock a competitive advantage for the UK life sciences sector.

c) Facilitate data collection in the real world, supporting the approval process.

Rescheduling psilocybin would facilitate the collection of real world data on the use of psilocybin within the clinic. The nature of psilocybin is such that evidence collection of this type is much more indicative of its use to patients, the use of Randomised Controlled Trials in the case of psilocybin and the psychedelics is far too restrictive. The MHRA are also now accepting the submission of real world evidence meaning that further data could be collected to support and facilitate a product reaching market through the normal clinical trials process established in the UK. Gathering data in this way will lead to increased understanding of the different possible indications and accelerate the development of further clinical trials down the line.

d) Allow for medical professionals to make their own decisions on whether or not prescribe the drug as a special without government restriction, as is already possible with drugs not within Schedule 1.

Drugs that are outside of Schedule 1 can be prescribed by a medical doctor as a 'special' before any product containing it reaches market authorisation. These decisions are made on a case by case basis by the prescribing physician in light of their college's clinical guidance and their own personal expertise and discretion. Psilocybin's current Schedule 1 status precludes such prescriptions without reason. If psychiatrists were able to prescribe psilocybin as a 'special', because it was in Schedule 2, individuals suffering from depression, veterans suffering from post traumatic stress disorder and those with depression and anxiety related to terminal cancer diagnoses would be potentially be able to access psilocybin, dramatically reducing their suffering and possibly saving their lives, if their physician thought it appropriate to prescribe. As it stands the Home Office is blocking the ability for psychiatrists to make their own informed responsible clinical decisions for their patients welfare.

e) Remove Home Office impediments on an issue concerning the DHSC and medical colleges.

The issue of access to medicines should not be blocked by the Home Office on criminal grounds, the Home Office needs to get out of the way and let medical professionals make their own decisions without Home Office obstruction.

10. Rescheduling psilocybin would not:

a) Increase illegitimate or irresponsible use or increase diversion.

There is no evidence of increased diversion of Schedule 2 substances from clinical research and practice due to the controls placed upon storage, transport and record keeping. Psilocybin is not a take-home medication and requires administration by trained professionals in controlled environments only once or twice rather than a daily maintenance treatment, further reducing the risk of diversion. In the UK population use of psilocybin containing mushrooms is low and there is no evidence of users developing a dependency. Psilocybin mushrooms grow wild throughout the United Kingdom, and are easy to cultivate in small containers in people's homes meaning that due to ease of illegitimate access psilocybin does not represent an opportunity for profit motivated gangs and criminal individuals. Allowing for prescription is more likely to reduce the numbers of people accessing psilocybin through illegitimate routes, reducing risks.

b) Change criminal penalties on the possession and supply of psilocybin by changing its Class A status under the Misuse of Drugs Act 1971.

The Schedule (Misuse of Drugs Regulations 2001) and Class (Misuse of Drugs Act 1971) of a controlled drug are independent of one another. Many drugs remain in Class A while in Schedule 2, such as heroin and cocaine. Rescheduling of psilocybin would have no effect upon its Class A status and thus criminal penalties for possession and supply will remain unchanged and affected, whilst psychiatrists will be able to use their discernment on prescription to

patients in legitimate need. Psilocybin is not a take-home medication and requires administration by trained professionals in controlled environments only once or twice rather than a daily maintenance treatment, further reducing the risk of diversion.

c) <u>Disincentivise companies from developing medical products containing psilocybin and taking them through the normal approvals process of the MHRA.</u>

There is concern that if psilocybin was rescheduled, and thus able to be prescribed to patients ahead of a product reaching market authorisation, companies developing medical products containing psilocybin would be disincentivised from pursuing market authorisation through the normal MHRA route. This is not the case for a number of reasons.

These concerns are a result of the situation concerning CBPM. In the case of CBPM, which were rescheduled and thus able to be prescribed from 2018, only 4 prescriptions have been given on the NHS whilst the majority is obtained privately and few companies are pursuing a market authorisation for their products through the MHRA route. The situation with psilocybin is different due to the differences in the molecules, their mechanisms of action and routes and contexts of administration. Simply, CBPM are take-home ongoing prescriptions with complex formulation requirements for different relatively small cohort conditions meaning that the reward for reaching market authorisation with such a product is outweighed by the costs associated with the clinical trials required to move through the usual 3 phase approval process. In the case of psilocybin, which requires relatively few dosings in a controlled environment with trained facilitators, for a number of conditions with relatively large cohorts, the potential market size is incentive enough to develop a novel and effective product with treatment specific wrap-around care as a single intervention.

Another disincentive to pursuing market authorisation for CBPM has been the growing global interest in adult use cannabis markets. Many of the CBPM producers assume that cannabis will be available for adult use within the next 10 years and as such see no reason to pursue a market authorisation costing tens of millions of GBP which will later become obsolete and bring no return on their investment. The risk is simply too high. The same ideas are not present amongst psilocybin companies who view their products as medical interventions requiring wrap-around care and support from trained professionals in controlled environments.

Market authorisation through the normal MHRA approval process is required before NICE will consider whether a medical product is cost-effective and recommended for NHS roll out and so drug development companies who have invested millions of GBP in development of a product containing psilocybin will still need to push their product through the normal process in order to reach market authorisation before they can get reimbursement and achieve the mass roll out and large contracts required make back their financial investment in the product.

Market protection post market authorisation is the real incentive for companies developing new drugs. The company that brings a product to market will receive 10 years of market protection before a generic of their product will be able to apply for market authorisation using data form the original sponsor, allowing for the recuperation and return on their investment. Rescheduling psilocybin would not interfere with this motivation to seek market authorisation.

A number of psilocybin-containing products are already being developed, for example COMPASS Pathways product COMP360 is in Phase 3 trials, meaning that it is set to reach the market around 2025. Some of these products, with their novel formulations, routes of administration, stipulations concerning wrap-around care such as the psychotherapeutic preparation and integration required, and so forth mean that even if the generic molecule psilocybin is rescheduled there will still be commercial motivation to seek market authorisation for a product through the normal MHRA route. The rescheduling of psilocybin would simply allow for the prescription of these products ahead of market authorisation, meaning patients in dire need of treatment can obtain access ahead of a product reaching market authorisation, as well as rapidly reducing barriers to research by aligning controls with the evidence.

11. Conclusions

Psilocybin's Schedule 1 status not only hinders research but also patient access. The Home Office presides over an area of policy that concerns the Department of Health and Social Care, and ultimately doctors and patients. The medical community of prescribers, and their colleges, should be unimpeded by the Home Office in their ability to use their discretion and expertise on whether or not it is appropriate to prescribe a promising compound.

We know that psilocybin is a promising treatment for depression. Depression is the largest contributing factor to suicide. On an average week 125 people in the UK take their own lives. Over the course of just two years, the time predicted it will take for psilocybin to reach the market, the number reaches 13,000 people. Those suffering in Australia, Canada and some US States no longer have to wait, but UK patients do.

It is unethical for the Home Office to perpetuate the scheduling of a compound which could save lives. If psilocybin was an oncology medicine with this safety profile and promise this level of control would not be tolerated by the medical community, showing the ongoing disparity between physical and mental health, when a loss of life through suicide can be just as devastating as one lost to cancer.

The scheduling of psilocybin has never been based on an assessment of the evidence. Its Schedule 1 status is incommensurate with its medical utility and safety profile. It is simply an accident of history. The Home Office should act immediately to commission an urgent ACMD review of the evidence for psilocybin's harms and medical utility with a view to rescheduling.

Annex 1.

Clinical Trials with Psilocybin in North America and Europe

Completed and Ongoing

(2006 - 24/05/2023)

The current evidence has been considered enough for:

Australia - In February 2023 the Australian TGA rescheduled psilocybin and MDMA, allowing licensed psychiatrists to prescribe them for the treatment of depression and PTSD respectively from July.

USA - In 2018 the United States' FDA already granted psilocybin and MDMA Breakthrough Therapy status for depression and PTSD respectively, fast tracking them through the process to medical access, meaning they could both reach market authorisation by 2025. States including Oregon and Colorado have legalised access to professionally guided psilocybin sessions for adults over the age of 21.

Canada - In January 2022 the Special Access Program in Canada came into effect, allowing psychiatrists to apply for licences to prescribe psilocybin and MDMA to named patients ahead of market authorisation of a medical product - patients have already begun to receive prescribed access.

Completed Clinical Trials Involving Psilocybin Listed by Date

Table 1. Completed Contemporary Clinical Trials Involving Psilocybin (post 2006)

Study	**Indication and sample size**	**Design**	**Main efficacy outcome**
Moreno et al (2006)	Obsessive compulsive disorder, n=9	Single-arm, within subjects, variable doses. Up to four doses of psilocybin	All patients showed improvements within 24 h of a treatment but no effect of dose.
Grob et al (2011)	Anxiety and depression in end-stage cancer, *n*=12	DB-RCT, crossover, inert placebo. Single dose of psilocybin.	Significant reductions in trait anxiety at 3 months and depression at 6 months.
Johnson et al (2014)	Long-term chronic tobacco smoking, *n*=15	Open-label. Up to three doses of psilocybin after four CBT sessions.	80% of sample abstinent at 6 month follow-up.

Bogenschutz et al (2015)	Alcohol dependence, *n*=10	Open-label. Up to two doses after seven motivational therapy sessions.	Significant decrease in drinking behaviors for up to 9 months.
Carhart-Harris et al (2016)	Treatment-resistant MDD, *n*=12+study extension to *n*=20	Open-label. Two doses of psilocybin.	Significant decreases in depressive symptoms for up to 6 months.
Ross et al (2016)	Anxiety and depression related to life-threatening cancer, *n*=29	DB-RCT, crossover, niacin=active placebo. Single dose of psilocybin.	Significant decreases in anxiety and depression *vs* niacin at 7 weeks (pre crossover) and sustained for 6.5 months.
Griffiths et al (2016)	Anxiety and depression related to life-threatening cancer, *n*=51	DB-RCT, crossover, VLD psilocybin=control. Single dose of psilocybin.	Significant decreases in anxiety and depression *vs* VLD at 5 weeks (pre crossover). Effects sustained for 6 months.
Davis et al (2020)	Major Depressive Disorder, *n*=27	DB-RCT, waiting list controlled (8 weeks), Two psilocybin sessions (session 1: 20mg/70 kg; session 2: 30mg/70 kg), 11 hours psychotherapy.	Clinically significant antidepressant response to psilocybin therapy persisted for at least 4weeks, with 71% of the participants continuing to show a clinically significant response (≥50% reduction in GRID-HAMD score) at week 4 of follow-up.
Anderson et al (2020)	Demoralized older long-term AIDS survivor men *n*=18	Open-label, group therapy comprising 8–10 group therapy visits and one psilocybin administration visit (0·3–0·36 mg/kg po)	Clinically meaningful change in demoralization from baseline to 3-month follow-up.

Carhart-Harris et al (2021)	Major Depressive Disorder, *n*=59	Phase 2, DB-RCT, 2 doses of 25 mg of psilocybin 3 weeks apart plus 6 weeks of daily placebo vs two separate doses of 1 mg of psilocybin 3 weeks apart plus 6 weeks of daily oral escitalopram; all the patients received psychological support.	Change in depression scores on the QIDS-SR-16 at week 6 (the primary outcome) did not differ significantly between the trial groups.
Schindler et al (2021)	Migraine, *n*=10	DB-RCT, cross-over , adults with migraine received oral placebo and psilocybin (0.143 mg/kg) in 2 test sessions spaced 2 weeks apart. Headache Diaries.	Reduction in weekly migraine days from baseline was significantly greater after psilocybin than after placebo.
Goodwin et al (2022)[21]	Treatment-resistant depression, *n*=233	DB-RCT, 25 mg, 10 mg, or 1 mg and psychological support.	Psilocybin at a single dose of 25 mg, but not 10 mg, reduced depression scores significantly more than a 1-mg dose over a period of 3 weeks.
Von Rotz et al (2023)[22]	Major Depressive Disorder, *n*=52	DB-RCT, either a single, moderate dose (0.215 mg/kg body weight) of psilocybin or placebo in conjunction with psychological support.	Significant reduction in depression symptoms at 14 days after the intervention compared to placebo.

Abbreviations: DB-RCT, double-blind randomised controlled trial; VLD, very low dose.

Ongoing Clinical Trials Involving Psilocybin Listed by Database

The EU Clinical Trials Register lists the following clinical trials of psilocybin as ongoing as of 24/05/23:

Table 2. Ongoing Clinical Trials Involving Psilocybin within the UK and EU

EudraCT no.	**Study title**	**Medical condition**	**Results**
2018-003382-34	Prophylactic effects of psilocybin on chronic cluster headache: an open-label clinical trial and neuroimaging study.	Chronic cluster headache.	Not yet available.
2017-003288-36	The Safety and Efficacy of Psilocybin in Participants with Treatment Resistant Depression (P-TRD)	Treatment Resistant Depression (P-TRD)	Not yet available.
2020-001348-25	A multicentre study to assess safety and efficacy of psilocybin in patients with treatment-resistant depression following completion of COMP 001 and COMP 003 trials (P-TRD LTFU)	Treatment-Resistant Depression (P-TRD)	Not yet available.
2018-003573-97	A randomised, placebo controlled trial of psilocybin in treatment resistant depression: A feasibility study	Major depressive disorder	Not yet available.
2019-004054-28	Psilocybin as a Treatment for Anorexia Nervosa: A Pilot Study	Anorexia Nervosa	Not yet available.
2018-002577-22	The safety and efficacy of psilocybin as an adjunctive therapy in participants with treatment-resistant depression	Treatment-Resistant Depression (P-TRD)	Not yet available.
2019-003984-24	A phase II randomized, double-blind, active placebo-controlled parallel group trial to examine the efficacy and safety of psilocybin in treatment-resistant major depression	Treatment-Resistant Depressive Episode or Treatment-Resistant Recurrent Depressive Disorder of moderate to severe degree without psychotic features	Not yet available.
2020-002790-94	The Effect of Psilocybin on MDD Symptom Severity and Synaptic Density – A Single Dose Randomised, Double Blind, Placebo-Controlled Phase 2 Positron Emission Tomography Study	Major Depressive Disorder	Not yet available

2020-000829-55	Can a one-off administration of psilocybin reduce alcohol intake in patients with alcohol use disorder? A randomised, double-blinded, placebo-controlled clinical trial.	Alcohol dependence syndrome	Not yet available
2018-004480-31	Psilocybin versus ketamine – fast acting antidepressant strategies in treatment-resistant depression.	Treatment resistant depression	Not yet available
2012-004579-37	Animal and human serotonergic model of schizophrenia: validity evaluated by qEEG and fMRI.	Healthy Volunteers	Not yet available
2020-005037-32	Psilocybin - a strategy of rapid antidepressant response in depression comorbid with cancer, a randomised double-blind study with the possibility of entering open extension.	Depressive disorder comorbid with cancer	Not yet available
2021-000041-40	A study to investigate the effects of repeated low doses of psilocybin and ketamine on cognitive and emotional dysfunctions in Parkinson's disease and to understand its mechanism of action.	Parkinson's disease	Not yet available
2021-002909-10	The impact of psilocybin on pain in fibromyalgia patients and healthy volunteers: a multicenter trial.	Fibromyalgia	Not yet available
2021-006233-19	Efficacy and safety of COMP360 psilocybin therapy in anorexia nervosa: a proof-of-concept study.	Anorexia Nervosa	Not yet available
2021-006200-33	A 24-Week, Multicentre, Randomised, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 2 Clinical Trial to Evaluate Efficacy and Safety of Psilocybin-Assisted Psychotherapy in Adults with Alcohol Use Disorder.	Alcohol Use Disorder	Not yet available

The N.I.H U..S National Library of Medicine Clinical Trials Register (clinicaltrials.gov) lists the following clinical trials of psilocybin as ongoing in the North American region as of 20/10/21:

Table 3. Ongoing Clinical Trials Involving Psilocybin in North America

NCT Number	Title	Conditions	Study Results
NCT05592379	Consciousness, Psilocybin, and Well-Being	Healthy|Psychedelic Experiences|Sleep	No Results Available
NCT04501653	Precision Functional Brain Mapping in Psilocybin	Psilocybin	No Results Available
NCT05322954	Study of the Safety and Feasibility of Psilocybin in Adults With Methamphetamine Use Disorder	Methamphetamine Use Disorder|Substance-Related Disorders|Chemically-Induced Disorders|Substance Use Disorders|Stimulant-Use Disorder	No Results Available
NCT05554094	Psilocybin for the Treatment of Veterans With Post-Traumatic Stress Disorder	PTSD|Stress Disorders, Traumatic|Stress Disorders, Post-Traumatic|Trauma and Stressor Related Disorders|Mental Disorder	No Results Available
NCT05546658	Effects of Psilocybin in Obsessive Compulsive Disorder	Obsessive-Compulsive Disorder	No Results Available
NCT05847686	Psilocybin-Assisted Therapy for the Treatment of Cancer-Related Anxiety in Patients With Metastatic Cancer	Hematopoietic and Lymphoid System Neoplasm|Metastatic Malignant Solid Neoplasm	No Results Available
NCT04932434	Psilocybin Therapy for Depression and Anxiety in Parkinson's Disease	Parkinson Disease|Depression|Anxiety	No Results Available
NCT05478278	An Evaluation of Psilocybin's Effect on Cardiac Repolarization and the Effect of Food on Psilocybin's Pharmacokinetics	QTc Interval|Pharmacokinetics	No Results Available
NCT05399498	Psilocybin in Co-occurring Major Depressive Disorder and Borderline Personality Disorder	Borderline Personality Disorder|Major Depressive Disorder	No Results Available

NCT05065294	Psilocybin Therapy for Depression in Bipolar II Disorder	Bipolar II Disorder	No Results Available
NCT04593563	The Safety and Efficacy of Psilocybin in Cancer Patients With Major Depressive Disorder	Major Depressive Disorder	No Results Available
NCT05305105	Effects of Psilocybin in Post-Treatment Lyme Disease	Post-Treatment Lyme Disease|Chronic Lyme Disease|Lyme Disease, Chronic	No Results Available
NCT04982796	Psilocybin-Enhanced Psychotherapy for Methamphetamine Use Disorder	Amphetamine-Related Disorders	No Results Available
NCT05866471	Pairing Psilocybin With Trans Auricular Vagus Nerve Stimulation	Healthy|Psychedelic Experiences|Vagus Nerve Stimulation	No Results Available
NCT03356483	Efficacy of Psilocybin in OCD: a Double-Blind, Placebo-Controlled Study.	Obsessive-Compulsive Disorder	No Results Available
NCT05381974	The Effects of Psilocybin on Self-Focus and Self-Related Processing in Treatment Resistant MDD	Treatment-Resistant Major Depressive Disorder	No Results Available
NCT05163496	Frontline Clinician Psilocybin Study	Burnout, Caregiver|Burnout, Professional|COVID-19|Depression|Post Traumatic Stress Disorder|Moral Injury	No Results Available
NCT03300947	Psilocybin for Treatment of Obsessive Compulsive Disorder	Obsessive-compulsive Disorder (OCD)	No Results Available
NCT04123314	Psilocybin for Depression in People With Mild Cognitive Impairment or Early Alzheimer's Disease	Depressive Symptoms|Depression|Alzheimer Disease|Mild Cognitive Impairment	No Results Available

NCT05370911	Effects of Repeated Psilocybin Dosing in OCD	Obsessive-Compulsive Disorder	No Results Available
NCT05220410	The Safety and Efficacy of Psilocybin in Patients With Treatment-resistant Depression and Chronic Suicidal Ideation	Treatment Resistant Depression|Suicidal Ideation	No Results Available
NCT05301608	Effects of Psilocybin on Electrophysiology and the Dynamic Content of Thought	Healthy	No Results Available
NCT05265546	Investigating the Mechanisms of the Effects of Psilocybin on Visual Perception and Visual Representations in the Brain	Perception Disorders	No Results Available
NCT03554174	Psilocybin - Induced Neuroplasti in the Treatment of Major Depressive Disorder	Major Depressive Disorder	No Results Available
NCT05224336	Psilocybin-assisted Therapy for Phantom Limb Pain	Phantom Limb Pain	No Results Available
NCT03341689	Psilocybin for the Treatment of Migraine Headache	Migraine Headache	No Results Available
NCT05733546	A Phase II, Multicentre, Randomised, Double-blind, Controlled Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Efficacy of COMP360 in Participants With Major Depressive Disorder With One Prior Treatment Failure	Major Depressive Disorder	No Results Available
NCT04218539	Repeat Dosing of Psilocybin in Migraine Headache	Migraine Headache	No Results Available

NCT04433845	The Safety and Efficacy of Psilocybin in Participants With Type 2 Bipolar Disorder (BP-II) Depression.	Treatment Resistant Depression	No Results Available
NCT04950608	Pilot Study of Psilocybin-Assisted Therapy for Demoralization in Patients Receiving Hospice Care	Hospice|Psilocybin|Demoralization|Terminal Illness|Cancer-related Problem/Condition|Psychotherapy|Terminal Cancer|Cancer Terminal	No Results Available
NCT04522804	Study of Psilocybin Enhanced Group Psychotherapy in Patients With Cancer	Cancer	No Results Available
NCT02037126	Psilocybin-facilitated Treatment for Cocaine Use	Cocaine-Related Disorders	No Results Available
NCT03806985	Effects of Psilocybin in Concussion Headache	Post-Traumatic Headache	No Results Available
NCT04620759	Psilocybin Treatment of Major Depressive Disorder With Co-occurring Alcohol Use Disorder	Major Depressive Disorder|Alcohol Use Disorder	No Results Available
NCT04161066	Adjunctive Effects of Psilocybin and a Formulation of Buprenorphine	Opioid Use Disorder	No Results Available
NCT04410913	Pilot Trial of Visual Healing® in Psilocybin-assisted Therapy for Alcohol Use Disorder	Alcohol Use Disorder	No Results Available
NCT02243813	Effects of Psilocybin-facilitated Experience on the Psychology and Effectiveness of Professional Leaders in Religion	Healthy	No Results Available
NCT05317689	Comparing the Effects of Psilocin and Psilocybin in Healthy Adults	Healthy	No Results Available

NCT04424225	Visual Surround Suppression and Perceptual Expectation Under Psilocybin	Perception Disturbance|Visual Suppression|Psychedelic Experiences	No Results Available
NCT05042466	Northwest Therapies Trauma Psilocybin Study Compassionate Use Study	Trauma, Nervous System	No Results Available
NCT02981173	Psilocybin for the Treatment of Cluster Headache	Cluster Headache	No Results Available
NCT05557643	PAPR: PAP + MBSR for Front-line Healthcare Provider COVID-19 Related Burnout	Depression|Burnout, Professional	No Results Available
NCT05035927	Evaluation of Psilocybin (TRP-8802) in the Treatment of Binge Eating Disorder	Binge Eating Disorder	No Results Available
NCT01943994	Psilocybin-facilitated Smoking Cessation Treatment: A Pilot Study	Nicotine Dependence	No Results Available
NCT05506982	Psilocybin Combined With Multidisciplinary Palliative Care in Demoralized Cancer Survivors With Chronic Pain	Hematopoietic and Lymphoid Cell Neoplasm|Malignant Solid Neoplasm	No Results Available
NCT05698511	Neural and Physiological Correlates of Psychedelic Sub-states	Psychedelic Experiences|Neuroimaging|Healthy Volunteers	No Results Available
NCT05220046	Palliadelic Treatment to Reduce Psychological Distress in Persons With Inoperable Pancreatobiliary Cancer	Pancreas Cancer|Biliary Tract Cancer|Psychological Distress	No Results Available
NCT05398484	Psilocybin Therapy in Advanced Cancer	Advanced Cancer	No Results Available

NCT05128162	Open-label Study to Assess the Safety and Efficacy of TRP-8802 With Psychotherapy in Adult Participants With Fibromyalgia	Fibromyalgia	No Results Available
NCT04433858	An Open Label Study of the Safety and Efficacy of Psilocybin in Participants With Treatment-Resistant Depression (P-TRD)	Treatment Resistant Depression	No Results Available
NCT05452772	5-HT2A Agonist Psilocybin in the Treatment of Tobacco Use Disorder	Tobacco Use Disorder	No Results Available
NCT05312151	The Safety and Tolerability of COMP360 in Participants With Post-traumatic Stress Disorder	Post Traumatic Stress Disorder	No Results Available
NCT05481736	Efficacy and Safety of COMP360 Psilocybin Therapy in Anorexia Nervosa: a Proof-of-concept Study	Anorexia Nervosa	No Results Available
NCT05385783	A Study of a Psilocybin Analog (CYB003) in Healthy Participants With and Without Major Depressive Disorder	Major Depressive Disorder	No Results Available
NCT03866174	A Study of Psilocybin for Major Depressive Disorder (MDD)	Depressive Disorder, Major	No Results Available
NCT05711940	Efficacy, Safety, and Tolerability of Two Administrations of COMP360 in Participants With TRD	Treatment Resistant Depression	No Results Available

NCT05624268	Efficacy, Safety, and Tolerability of a Single Administration of COMP360 in Participants With TRD	Treatment Resistant Depression	No Results Available
NCT05585229	Standardised Natural Psilocybin-assisted Psychotherapy for Tapering of Opioid Medication	Opioid Dependence|Chronic Pain	No Results Available
NCT05243329	Investigating the Therapeutic Effects of Psilocybin in Treatment-Resistant Post-Traumatic Stress Disorder	Treatment Resistant Disorders|Post Traumatic Stress Disorder	No Results Available
NCT05832255	An Investigation of Psilocybin on Behavioural and Cognitive Symptoms of Adults With Fragile X Syndrome	Fragile X Syndrome|Behavior|Cognitive Dysfunction	No Results Available
NCT05029466	Psilocybin for Treatment-Resistant Depression	Treatment Resistant Depression	No Results Available
NCT05594667	Effect of SSRIs on Response to Psilocybin Therapy	Depression|Major Depressive Disorder|Mild Depression|Moderate Depression|Depressive Disorder	No Results Available
NCT05710237	Does Psilocybin Require Psychedelic Effects to Treat Depression?	Treatment-resistant Depression	No Results Available
NCT05259943	Microdosing Psychedelics to Improve Mood	Persistent Depressive Disorder, Dysthymia	No Results Available
NCT05646303	Psilocybin-Assisted Psychotherapy in Adults With Alcohol Use Disorder (AUD)	Alcohol Use Disorder	No Results Available

Annex 2.

Public Attitudes to Psilocybin report summary by Psilonautica and DrugScience.

Psilo Nautica

Drug Science

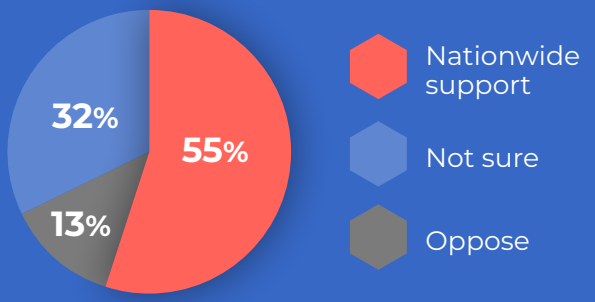
Public Attitudes to Psilocybin-Assisted Therapy

Psilo Nautica

Drug Science

Support for Rescheduling

To what extent **would you support** or **oppose the government relaxing restrictions on research into the medical use of magic mushroom-based treatments** (psilocybin-assisted therapies) for mental health conditions if this didn't affect how it was classified in criminal law (e.g. as a class A drug)?



Support for relaxing research restrictions:

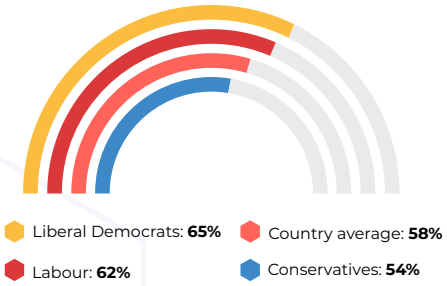
Country average **55%**

London	Midlands & Wales	Scotland
52%	**51%**	**55%**
Rest of South	North	Northern Ireland
60%	**52%**	**59%**

Support for changing the law to allow people with terminal illnesses to access **psilocybin-assisted therapy** **58%**

12% oppose

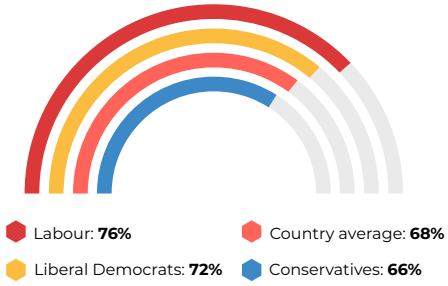
30% not sure



When informed about **findings from clinical research**, and moves to allow limited patient access in Canada, **support jumped to** **68%**

9% oppose

23% not sure



59% of Brits would **consider psilocybin-assisted** therapy if offered to them

Changing the law to allow **military veterans suffering from psychiatric distress** to legally access psilocybin-assisted therapies

55% support

13% oppose

32% not sure

By age

18-24:	25-49:
60% support	**55%** support
13% oppose	**10%** oppose
50-64:	65+:
55% support	**51%** support
15% oppose	**17%** oppose

Key Findings

- Majority support, across demographics, for relaxing research restrictions:

  55% Support
  15% Oppose
  31% Not sure

- Majority support, across demographics, for changing the law to allow medical use of psilocybin-assisted therapy in:

  Terminally ill patients 58%
  Armed forces veterans 55%

- Support for access for terminally ill patients rises to **68%** when respondents are informed about research and policy developments in Europe and North America

- Most Brits **(59%)** would **'probably'** or **'definitely'** consider psilocybin-assisted therapy if they had a condition for which there was strong evidence it would be effective

- Among those unlikely to consider psilocybin-assisted therapy, significant numbers base their hesitance on misunderstanding (e.g., **24%** are worried about becoming addicted - in fact, psilocybin is not addictive, and psilocybin therapy involves just one or two doses)

Findings in full

Research into the therapeutic benefits of psilocybin will be significantly facilitated by **moving psilocybin to Schedule 2 of the Misuse Drugs Regulations.**

We asked the public:

To what extent would you support or oppose the government relaxing restrictions on research into the medical use of magic mushroom-based treatments (psilocybin-assisted therapies) for mental health conditions if this didn't affect how it was classified in criminal law (e.g. as a class A drug)?

55% nationwide support

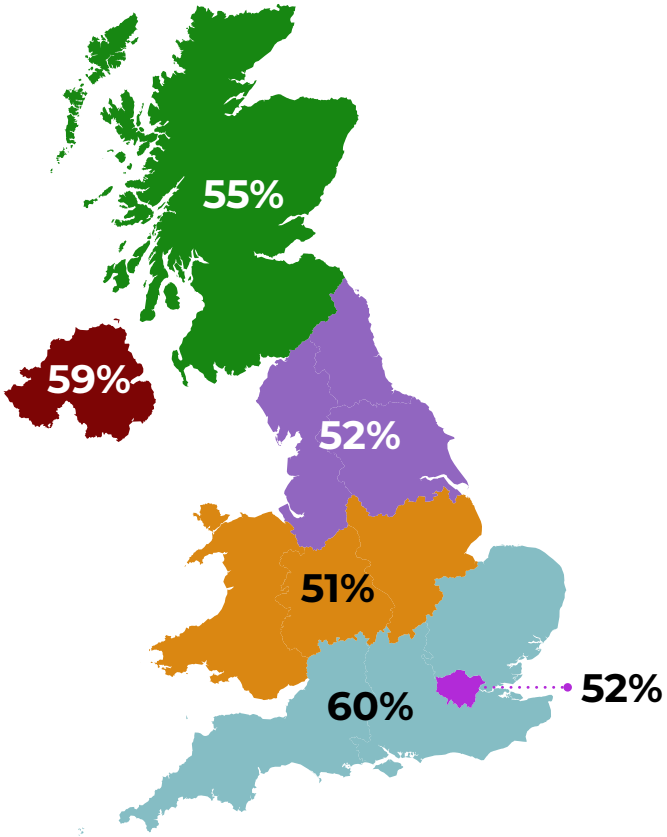
13% opposition

31% not sure

Support for relaxing research restrictions

Country average **55%**

- Conservative voters: **51%**
- Labour voters: **60%**
- Lib Dem voters: **64%**



Approval for changing the law to allow **people with terminal illnesses** to access psilocybin-assisted therapy

58%

12% oppose

30% not sure

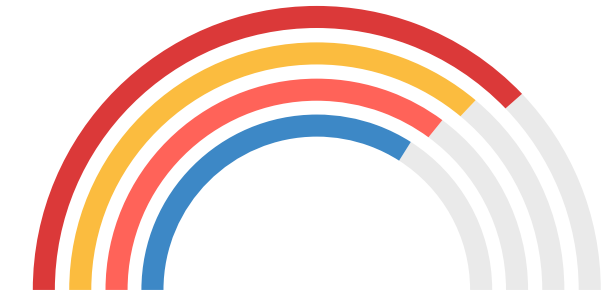
- Liberal Democrats: **65%**
- Country average: **58%**
- Labour: **62%**
- Conservatives: **54%**

With psilocybin only having very recently been subject to media attention, we anticipated high rates of 'not sure'. So, at the end of the survey we provided respondents with information about clinical research into psilocybin, its 'Breakthrough Therapy' designation in the US, and the Canadian government's decision to allow 28 terminally ill patients to access psilocybin-assisted therapy. When provided with this additional information, support for changes to the law to allow terminally ill patients to access psilocybin-assisted therapy rose to:

68%

9% oppose

23% not sure



- Labour: **76%**
- Country average: **68%**
- Liberal Democrats: **72%**
- Conservatives: **66%**

If you had a bad bout of depression, **how confident would you feel about trying the following treatments**?

Antidepressants

46% **lacked** confidence in antidepressants

Of these:

58% would **consider** psilocybin-assisted therapy

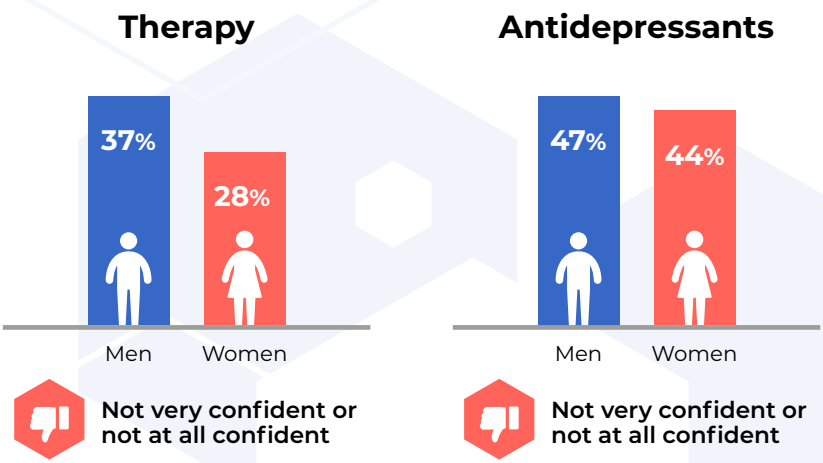
Therapy

33% **lacked** confidence talking therapy

Of these:

55% would **consider** psilocybin-assisted therapy

Men are more sceptical about traditional treatments:



The reverse is true for psilocybin-assisted therapy. If they had a medical condition where there was strong evidence that psilocybin-assisted therapy could be effective:

62% of men would consider it

55% of women would consider it

Drug Science

For more information about Drug Science,
please visit **www.drugscience.org.uk**

Registered Office: 130 Wood Lane, London, EC2v 6DL
Company Number: 08032149
Registered Charity Number: 1150449

DrugScienceISCD @Drug_Science

Annex 3.

Open letter of Support signed by the Royal College Psychiatrists, CALM, SANE and others.

CONSERVATIVE
DRUG POLICY
REFORM GROUP

www.cdprg.co.uk · info@cdprg.co.uk · @CDPRGUK

The Rt Hon Chris Philp MP
Home Office
2 Marsham Street
London, SW1P 4DF

12th May 2023

Dear Mr Philp,

Psilocybin Access Rights

The undersigned urge you to commission a high priority ACMD review of the evidence for psilocybin's status as a Schedule 1 controlled substance under the Misuse of Drugs Regulations 2001, with a view to rescheduling.

The evidential basis for psilocybin's current status has never been reviewed since the substance was first controlled over 50 years ago. We recognise the urgent and medically justified need to reschedule psilocybin under the 2001 Regulations. It is unethical to delay any longer. A review of the evidence of psilocybin's harms and utility with a view to rescheduling should be undertaken immediately.

Depression is one of the most socially, medically and economically burdensome diseases of the modern world. It is the single largest cause of global disability and the leading contributor to suicide. An average of 18 people take their own lives every day. Up to one-third of people with depression do not respond to multiple courses of medication, an estimated 1.2 million adults in the UK living with 'treatment-resistant depression'. The direct treatment and unemployment costs to the UK associated with depression in 2020 have been estimated at £10 billion. The human and economic burden of this condition is profound and there are clear benefits in supporting development of novel therapies that may be effective where all other treatments have failed. The Government has a moral imperative to actively support mental health research, including the development of promising drugs.

Clinical research suggests that psilocybin can be used safely and feasibly in the treatment of the most intractable forms of depression and other mental health conditions, and that it is likely to have lasting therapeutic benefits. There is a large body of epidemiological, experimental, and clinical data in the scientific literature to indicate that psilocybin is a relatively safe drug with very low toxicity and no known link to the development of physical dependence.

There are serious and considerable barriers to legitimate research associated with Schedule 1 regulations. While current legislation does not preclude scientific research with these drugs, it does make them significantly more difficult, time-consuming and costly to study. It is well known in the research community that the net burden of these barriers is sufficient to deter many research studies from ever taking place, and to substantially complicate and delay those that do. It is clear that Schedule 1 regulations impede the development of the scientific work required to bring a drug to market. These regulations are not appropriate for the legitimate study of drugs with low potential for abuse.

Considerable evidence should be required to justify regulatory controls that impede legitimate mental health research, but there was little robust evidence to support the initial scheduling decisions made in the early 1970s and the evidence for psilocybin's current status has never been reviewed. Today, the overwhelming scientific consensus is that psilocybin does not pose a major risk to the individual, public health or to social order. Its Schedule 1 designation is not morally, medically or economically appropriate.

We urge the Home Office to commission a high priority ACMD review of the evidence of psilocybin's harms and utility with a view to reschedule psilocybin under the 2001 Regulations.

Yours,

Cc:

The Rt Hon Rishi Sunak MP, The Prime Minister
The Rt Hon Steve Barclay MP, Secretary of State for Health and Social Care
The Rt Hon Johnny Mercer MP, Minister of State for Veterans' Affairs
Dr Owen Bowden-Jones, Chair of the Advisory Council on the Misuse of Drugs
Steve Brine MP, Chair of the Health and Social Care Committee
Dame Diana Johnson MP, Chair of the Home Affairs Committee