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Feature

Psychedelics in NHS services: exploring a model for real-world implementation of psilocybin

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Summary

Psychedelics are increasingly described as a new therapeutic approach in a variety of mental disorders including depression. Oral psychedelics such as psilocybin have an acute effect evolving over 6–8 h and are generally given in combination with psychological support. There is debate on the exact role of this support and how and by whom it should be delivered. This has significant implications for real-world implementation in health services post-licensing. In this feature, we discuss these issues and outline a model for psychological support delivery in publicly funded health services such as the National Health Service. We also suggest further research to explore the exact role of support in psilocybin treatment and identify the essential elements to direct service plans for clinical implementation. These steps are important: over recent decades, there have been few new treatments for depression, moreover, psychedelic drugs are appealing to patients, and accumulating data suggest that their efficacy may be long-lasting. However, realistic plans for implementation must be based on high-quality evidence and the needs of the whole patient population. This will ensure that these treatments, if licensed, are available not only for those able to pay but to all on an equitable basis.

Keywords

Psychedelic; psilocybin; psychedelic-assisted therapy; depression.

Psychedelics are increasingly being hailed as a new therapeutic approach in a variety of mental disorders,[1] including depression, eating disorders and post-traumatic stress disorder. Recent research data show efficacy in depression, particularly for psilocybin,[2] with evidence of benefits in clinical trials for participants with treatment-resistant depression (TRD), usually defined as depression failing to respond to two first-line antidepressants.[3]

In this feature, we focus on psilocybin, because we have hands-on research experience with this medication in ongoing studies at the National Institute for Health and Care Research (NIHR) Oxford Health Clinical Research Facility. However, psilocybin should be considered as an example, as there are other orally administered psychedelics for which similar issues arise. Psilocybin has an action evolving over a number of hours and is delivered in combination with some form of psychological support (also described as therapy or psychedelic-assisted therapy; PAT),[4] although this support may vary significantly among different studies and protocols.[5] This combination of drug and PAT raises two key areas of uncertainty with important implications for clinical implementation.

(a) Is psychotherapy and/or psychotherapeutic support *essential* for psychedelic drugs like psilocybin to improve patients' clinical outcomes?
(b) If so, *which kind* of psychotherapy/support is required and what are the essential elements?

The first is a scientific question about the underlying mechanism of action producing a beneficial effect after psilocybin administration, and addressing this issue will require a systematic and multidisciplinary approach to assess the available evidence and identify the best next steps for research. The second has key implications for clinical implementation and translation into real-world practice. The current research model of one-to-one support throughout the duration of the dosing day (approximately 6–8 h) has cost implications and therefore raises questions about how health systems such as the National Health Service (NHS) could implement it, if the treatment is proven effective. In the context of the UK government's recently published 10-year health plan for the NHS,[6] which emphasises 'a new model of care, fit for the future', we need to consider the clinical implementation of novel treatments and treatment delivery before licensing, to allow equitable care to everyone.

In this article, we consider the background to these issues, focusing on psilocybin as an example, and provide some suggestions for possible solutions in clinical settings such as the UK NHS, including an approach used by our research group which may provide a helpful model for real-world implementation.

What are the potential benefits of psilocybin in therapeutic use for TRD?

Trials of efficacy have generally been positive thus far. Phase 2 study results showed that a single dose of 25 mg of psilocybin reduced depression scores on the Montgomery–Åsberg Depression Rating Scale more than a comparison 1 mg at 3 weeks (mean difference −6.6, 95% CI: −10.2 to −2.9; $P < 0.001$).[3] Recent initial phase 3 results have been published as press releases (peer reviewed study results to follow) and also showed a positive although relatively modest effect measured on the Montgomery–Åsberg Depression Rating Scale at 6 weeks (COMP005 press release: single dose 25 mg versus inactive placebo, mean difference −3.6, 95% CI: −5.7 to −1.5; $P < 0.001$).[7] A further large-scale international phase 3 trial is ongoing (https://clinicaltrials.gov/study/NCT05711940) and the initial results of the two acute doses also show similar results on the same scale at 6 weeks (COMP006 press release, two doses of 25 mg *v* 1 mg, mean difference −3.8, 95% CI −5.8 to −1.8; $P < 0.001$).[8]

In clinical trials, psilocybin appears to be relatively safe and well tolerated in the short term, with the most common side-effects including transient headache, dizziness, nausea and fatigue.[9] However, possible lower-frequency delayed side-effects such as suicidal ideation and hallucinogen persisting perception disorder will need to continue to be actively monitored both in trials and post-licensing.[10] Recreational use data also suggest that longer-term

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effects may occur in non-clinical settings. In a mixed methods study of individuals selected because they self-identified as having experienced difficulties after using a psychedelic drug ($n = 608$, >95% in a non-clinical setting), participants reported that some of these were extended or longer-term challenges, most commonly described as emotional difficulties, which lasted beyond 3 years in 103 responses.[11] Although these reported data are from a different setting, and one less controlled than that of clinical trials, they support the importance of careful monitoring and reporting of adverse events, including in longer-term follow-up.

In addition to evidence of their efficacy, the potential of psilocybin and psychedelics in general as therapeutic agents is strengthened by a number of factors.

(a) Limited numbers of new drugs have been developed in psychiatry (including for TRD) in recent years, and so a new approach with a possible novel and longer-lasting mechanism of action seems promising. For example, psilocybin, as well as its direct pharmacological action (particularly at 5HT-2A receptors), may also have long-lasting neural effects. Supporting this hypothesis, studies suggest that even a single psychedelic experience can lead to persistent changes in brain network dynamics. For example, acute psilocybin seems to be associated with reduced connectivity in the default mode network but increased functional connectivity with other brain networks, and these changes may persist after administration, potentially reflecting a more flexible and integrated brain state.[12,13]
(b) Psychedelics are also appealing to the general population because of their long history of use as recreational drugs, which gives some limited real-world data on effects and side-effects. They are also similar to 'natural' substances such as so-called 'magic mushrooms' and ayahuasca.
(c) Their use has become part of a wider 'psychedelic culture',[14] providing a sense of support and a social identity which may be important in both recreational and research settings.
(d) The use of oral psychedelics such as psilocybin is also appealing for some people with mental health problems, as their use can be seen as a unique combination of pharmacological and psychological treatment. It is often believed by patient groups that medications are overused at the expense of psychological therapies, including in the treatment of depression, and so the model of combined psychedelic drug administration with psychological support is appealing. However, there is significant debate in this area: some researchers argue that psychedelic treatment should be better understood as PAT, a combination of psychological and pharmacological approaches, and not merely as a drug treatment;[1,15] whereas others argue for a primary pharmacological action with psychological support in place to ensure safety.[16]

What are the challenges in therapeutic psilocybin use?

Regulation and licensing

The particular background of psychedelics, with historic misuses, has resulted in an almost total ban on their use in research; in the past 20 years or so, research use has restarted but has been significantly restricted. The implementation of 'schedule I' Home Office licensing in the UK (and similar legislative frameworks in other countries) has restricted research and eventual access in clinical settings, causing significant delays in the research process.[17] However, there are some potential changes ahead: for example, the UK government is working with the Advisory Council on the Misuse of Drugs to reduce barriers to research such as that involving psychedelics, including piloting a system for licence exemptions in academic and NHS trial settings, with strict oversight.[18]

A key challenge in mental health is the implementation of effective treatments.[19] In most countries, use is restricted to specific research studies only (with allowance in some countries for 'compassionate use'), but there is one model of wider clinical service implementation: in Australia, regulations changed in 2023 to allow approved psychiatrists to prescribe psilocybin and MDMA for patients with TRD and treatment-resistant post-traumatic stress disorder, respectively.[20] This model requires prescribers to provide a treatment protocol that includes dosing and psychological support session information (the latter using models of PAT used in previous clinical trials) and is approved by a human research ethics committee and authorised by the Therapeutic Goods Administration before proceeding. However, the restrictions around psychological support are challenging for real-world implementation of psilocybin use in a publicly funded health service such as the NHS.

The role and type of psychological support

The debate over the exact role of psychological support creates difficulties in several ways. Psilocybin, like other psychedelics, produces acute psychological effects. These are often measured in clinical trials using rating scales, such as the 5-Dimensional Altered States of Consciousness Rating Scale, and there is some evidence that the intensity of these experiences may be correlated with subsequent therapeutic response.[21] In addition, other psychological symptoms (such as emotional breakthrough, connectedness and insightfulness) may also predict improvement.[22] These acute psychological symptoms can cause anxiety and distress during the dosing day which require psychological support and safety. However, a parallel argument is that psychological support or treatment is also essential as an integral part of the therapeutic process.

The presence of psychological support as part of psilocybin dosing complicates eventual licensing, as regulatory bodies such as the US Food and Drug Administration (FDA) and the Medicines and Healthcare products Regulatory Agency license drugs (and not psychological treatments or combinations). The uncertainty with respect to the rationale for psychological support also creates variability in the exact therapeutic components provided: is this purely to contain any negative aspects of the acute experience (such as anxiety, tearfulness or hallucinations), or is it also present as an essential therapeutic tool? Perhaps because of this uncertainty, there is also a lack of consistency in reporting of the exact type of support or therapy delivered. In many studies, this is often not well described, and it is difficult to identify which elements were involved,[23] although there are some exceptions.[24] Support usually involves elements of preparation, support during dosing and integration sessions afterwards, but the number, duration and content of sessions appear to vary significantly. This variability and lack of standardisation is an issue because the studies cannot inform us what the key 'active ingredients' of therapeutic support are or what 'dose' is required.[10] Some reviews have tried to summarise the existing data on the support or therapy used. A recent meta-analysis suggested no association between the amount of therapy/psychological support hours (during preparation and integration) and depressive outcomes,[25] and another meta-analysis indicated that improvement in depressive symptoms did not depend on which psychological protocol was used.[5] However, both analyses

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were limited by inconsistent reporting and missing data in the individual studies.

Staff skills required to support psilocybin treatment

More studies with better reporting addressing the specific elements of therapy or psychological support are needed. These data (Box 1) could also inform what specific psychotherapy skills are required (or whether standard clinical support as provided routinely in the NHS is sufficient), and therefore which staff are best placed most efficiently to provide this therapeutic support. In the absence of these data, research and ultimately clinical translation will rely on previous experience rather than high-quality evidence. For example, the FDA provides (non-binding) guidance that studies of psychedelics should use healthcare providers with at least graduate level experience and expertise in psychotherapy,[26] with at least one provider licensed to practise psychotherapy. The recently published Royal College of Psychiatrists' position statement on psychedelics for medical use[4] describes similar criteria where those administering psychedelics or providing any form of psychotherapy must be 'an appropriately trained and competent registered clinician'. In the accompanying guidance on clinical trials this is outlined as a therapist experienced in mental health/therapy settings who has also taken further training and experience in the delivery of psychological therapies.

In the UK, a clinician meeting these criteria would be a member of the team such as a doctor, registered nurse or clinical psychologist, who would also (as per FDA and RCPsych guidance) need to receive training specific to psychedelic-assisted psychotherapy as well as safety monitoring and supportive interventions. This is likely to restrict availability in NHS secondary care services, as the time involved would be significant and the staff specified by this guidance are generally in short supply. For example, in the UK, whereas overall the NHS workforce has grown by 23% between 2010 and 2023, nursing numbers fell substantially from 2010 to 2017, subsequently increasing only to 2010 levels. This led to changes in the skill mix (from a 60:40 ratio of registered nursing staff to support staff in 2012/2013 to a ratio of 40:60 in 2022/2023), and non-registered staff such as mental health practitioners and healthcare support workers now represent a greater proportion within the NHS.[27]

Long-term management of these patients and their treatments also has important implications for the NHS. Although some data suggest a longer-lasting benefit after a single dose of psilocybin, this effect may wane after some months.[28] More data and randomised controlled trial evidence are needed, but it seems likely that 'top-up' doses will be indicated, and the frequency of these may vary on an individual basis. Taken together, these requirements for therapist experience and qualifications risk driving the use of therapeutic psilocybin post-licensing beyond the capacity of an already stretched NHS, with the result that it may only be accessible in specialised centres via private healthcare provision.

What further research is needed?

Although there has been a surge in psychedelic research in recent years, mechanistic studies are needed to investigate not only the underlying biological processes but also the psychotherapeutic elements responsible for the therapeutic effects of psychedelics.[29]

This mechanistic work will be critical to enable us to understand the exact applications of psychedelics and how they can translate into real-world clinical services. Exploring mechanisms may involve synthesising a variety of different experimental approaches. Synthesis of multiple sources of evidence can be approached using the process of triangulation, which has been adopted in other areas in mental health.[30]

Box 1 Suggestions for next steps to investigate the role of psychological support in psilocybin administration in treatment-resistant depression

Improved reporting of therapeutic support in psilocybin trials:

(a) to investigate which components are essential for a beneficial outcome (and which are not);
(b) to identify the underlying mechanisms of change (which may require synthesis of different sources of evidence);
(c) to use these data to create evidence-based guidelines for psychological support and standardise this across trials;
(d) to determine which staff are most appropriate to provide this psychological support;
(e) to identify training and experience requirements for mental health staff to provide support.

Future research could compare outcomes for different approaches:

(a) therapeutic support alone versus psychedelic alone and the combination;
(b) different types of psychological support or psychotherapy in association with psychedelic drug administration.

Importance of research in the longer-term treatment of depression to ascertain:

(a) timing of initial doses;
(b) impact of 'top-up doses' for maintenance of effect;
(c) role of psychological support in long term psilocybin treatment;
(d) frequency of adverse events.

For psychological support specifically, assessment of which components are essential to develop protocols for treatment and definition of the skills will be required. However, current data and reporting are not sufficient for this type of analysis, although frameworks (such as use of the TIDieR checklist and ReSPCT guidelines) have been suggested.[23,31] Future research (Box 1) could compare outcomes for participants randomised to, for example, protocolised psychotherapy/support alone, psychedelic treatment alone (with usual NHS safety support) and combination psychotherapy/support and psychedelic treatment,[13,32] with more detailed reporting to allow analysis of the components and their outcomes.

Our experience as an illustrative example

In the absence of these data, we took a pragmatic approach to model the implementation of therapeutic psychedelic use in the NHS, and we present our experience here as an illustrative example which may be a useful model in other settings. The Oxford Health Clinical Research Facility is one of several UK sites for a phase 3 study of the efficacy, safety and tolerability of two administrations of psilocybin in patients with TRD, comparing doses of 25 mg, 10 mg and 1 mg and including a longer-term follow-up (ClinicalTrials.gov ID: NCT05711940). In agreement with the sponsor of the study, we took a different approach to delivering the full model of therapeutic support. Instead of adhering to the use of professionally registered staff only, we prioritised training and clinical experience. We used experienced research assistants, who were all psychology graduates with significant in-patient and out-patient experience (and were therefore very similar to 'mental health practitioners' in the NHS). All completed the same rigorous training for psychedelic therapy support[24] as therapists at the other sites in the trial. Following completion of training, they successfully delivered preparation sessions (1–2 h), support through the 6 h dosing sessions and then integration sessions, all delivered under close supervision by the clinical research team led by the principal investigator (K.A.S.), a consultant psychiatrist.

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Our experience is of one model of therapeutic support in a psilocybin research programme which uses NHS mental health staff, who are relatively numerous and readily available. The focus is on safety and psychoeducation, which form the bedrock of good clinical care in the NHS. The exact role of psychological support in psychedelic treatment is still unclear, and further research is needed to determine whether there are a smaller number of essential components and whether a lower 'dose' is possible. In the absence of these studies, we will need to continue to deliver therapeutic support as described in the current trials of psilocybin; however, in the meantime, our experience suggests the potential of a model of safely administering psilocybin on the standard psychological support 'dose' but – crucially for real-world implementation – using a more numerous and readily available category of mental health staff.

Next steps

In this feature, we have identified a number of areas in which more research is needed (Box 1). These include:

(a) improved reporting of psychological support in psychedelic trials, perhaps using existing guidelines;[31]
(b) investigating how different elements of the psychological support can affect the outcome of the psychedelic experience;
(c) standardising treatment across trials and creating evidence-based guidelines for clinical implementation;
(d) designing and implementing a training and/or experience requirement for mental health workers to qualify for providing psychedelic support (which could rely on milestones of training and clinical experience rather than general professional licensing).

However, we think that this will require joined-up and focused consideration rather than a piecemeal approach. This could take the form of a consensus process in which all stakeholders from a variety of backgrounds sit around the same table and define and agree on the criteria that should inform research prioritisation and unmet needs. Importantly, stakeholders should include not only clinicians but a wider spectrum of interested parties. A relevant model may be that of the Wellcome-funded GALENOS project (Global Alliance for Living Evidence on aNxiety, depressiOn and pSychosis; https://www.galenos.org.uk/). This is a structured methodological approach for assessing the evidence and identifying priorities for further research by incorporating existing types of evidence, including human and animal data, and different study designs with lived experience expertise throughout.[33] This approach should be supported by independent funders and may help to inform clinical practice as it allows novel insights and collaborative research prioritisation focused on the areas of greatest need.[34]

Whatever the model adopted, now is the time to focus the research field for psychedelic drugs such as psilocybin and to join forces to more clearly understand the underlying mechanisms of action and the exact role of psychological support, and their impact on translation into existing clinical settings such as the NHS.

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Data availability

Not applicable to this article as no new data were created or analysed in this study.

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Author contributions

The first draft of the manuscript was produced by K.A.S. with input from E.H. and A.C. All authors reviewed and contributed to subsequent versions and approved the final version.

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