Schedule 1 barriers to research in the UK: An in-depth qualitative analysis

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Abstract

Background: There is increasing research to suggest that certain Schedule 1 drugs, most notably psychedelics, can be effective in treating a range of mental health disorders. However, due to several practical, financial, and bureaucratic barriers, there is a lack of large-scale trials into their efficacy. This study aimed to explore the barriers, and any facilitators, to undertaking Schedule 1 research through examining the different positions Schedule 1 and other controlled drug researchers place themselves in, and the impact this has on their experiences.

Method: Semi-structured interviews were conducted with 12 participants. Eight Schedule 1 researchers and four researchers who conduct other controlled drug research. Participants were recruited via purposive and snowball sampling. Interview questions explored how participants’ experiences of controlled drug research were impacted by scheduling laws, and how they might differ from the other group.

Results: Using discourse analysis, four themes were identified. Three themes differentiated the two groups of researchers and their positions (differential burden of duties, the importance of privileges, and motivations); the differential burden of duties acted as a barrier to non-Schedule 1 researchers, whereas Schedule 1 researchers were better able to deal with this burden due to higher levels of motivation and more privileges (facilitating Schedule 1 research). One theme suggested solidarity between the groups; others acted as barriers to Schedule 1 research, with government officials preventing changes to drug legislation, and those lacking scientific understanding being discriminatory, causing difficulties getting Schedule 1 projects started.

Conclusion: Findings highlight the challenges that Schedule 1 researchers are currently facing and suggest that the government should commission an urgent review into this by the Advisory Council on the Misuse of Drugs to make Schedule 1 research process smoother and more accessible. For example, reducing the barriers to research of Schedule 1 substances so as to be in line with the regulations controlling those in Schedule 2.

Keywords
Schedule 1, misuse of drugs regulations 2001, UN convention, psychedelics

Introduction

The Misuse of Drugs Regulations (MDR, 2001) classify certain potentially medically beneficial drugs in Schedule 1 (S1), including psychedelics such as psilocybin (the active constituent of magic mushrooms), DMT (N, N-dimethyltryptamine, one of the active constituents of Ayahuasca) LSD (lysergic acid diethylamide) and MDMA (3,4-Methylenedioxymethamphetamine, Ecstasy), as well as several cannabinoids (those containing high levels of tetrahydrocannabinol and synthetic cannabinoid receptor agonists). Current scheduling gives the impression that these potential medicines have no medical value and a high likelihood of harm and misuse. As a result, these drugs cannot be stored, prescribed or researched without possession of a controlled drugs (CD) licence from the UK Home Office. In contrast, drugs in Schedule 2 (S2),

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such as cocaine, diamorphine (heroin) and ketamine, are considered to have medical value, but a high likelihood for harm and misuse.

Although careful precautions and record keeping for research into S2 drugs is required, they can be stored safely for research purposes and prescribed by health care professionals. Without the requirement for a CD licence, research is not unduly hindered. Drugs considered to have a high medical value and a low harm risk, such as buprenorphine and diazepam, are placed in Schedules 3–5. Restrictions on these drugs are lower still, and they are used frequently in medicine and researched widely (Freeman et al., 2018).

Considerable evidence shows that the MDR (2001) are not based on the scientific evidence of the risks of these drugs (Nutt et al., 2010; Rucker, 2015). For example, an extensive and detailed Multi-Criteria Decision Analysis (MCDA) of 20 legal and illegal drugs found that those in S1, such as LSD and psilocybin, were the least harmful to both users and society (Nutt et al., 2010). Counter-intuitively, S2 drugs, most notably heroin, cocaine and amphetamines, scored significantly higher on all 16 harm criteria. Research has found cocaine to have significant abuse liability, often resulting in cardiovascular problems, and death in extreme cases (Office for National Statistics, 2018; Pomara et al., 2012). Alcohol and tobacco, legal and sold commercially, were found to score amongst the highest. Similarly, amphetamines have been found to be associated with a range of adverse effects, including growth deficits, dependence, and brain abnormalities leading to motor and memory problems (Berman et al., 2008; Swanson et al., 2007). Whilst these studies provide a useful insight into the relative harms caused by scheduled drugs, the MDR (2001) also creates the perception of drugs being scheduled according to their medical value, and this needs to be reconsidered for a fuller and more accurate evaluation.

Recent evidence for the medical value of S1 drugs

Research demonstrates that there is likely to be therapeutic benefit associated with compounds found within this category. This is especially true for psychedelics which, when administered alongside psychotherapy, are being found to have promising therapeutic benefits for a range of psychiatric disorders (Breeksema et al., 2020; Fuentes et al., 2020; Nutt et al., 2020; Wheeler and Dyer, 2020). For example, in small trials, psilocybin assisted therapy administered in a clinically controlled environment has been found to be safe and effective in reducing the symptoms of severe and treatment-resistant depression (Carhart-Harris et al., 2016; Carhart-Harris et al., 2018; Gonda et al., 2021), obsessive-compulsive disorder- OCD (Moreno et al., 2006), and recently, has been hypothesised to have efficacy in post-traumatic stress disorder-PTSD (Krediet et al., 2020).

Furthermore, psilocybin assisted psychotherapy has shown beneficial effects on anxiety and depression in individuals with life-threatening diseases (Griffiths et al., 2016; Grob et al., 2011; Ross et al., 2016), and clinical trials are being conducted with MDMA for PTSD, alcoholism and other disorders (Mitchell et al., 2021; Yazar-Klosinski and Mitrofanow, 2017). Psychedelic-assisted psychotherapies are proving more beneficial for some patients compared with current antidepressant and anxiety medication, which are often associated with high levels of sub-syndromal symptoms, severe side-effects, and frequent relapses (Rush et al., 2006; Ferguson, 2001; Huh et al., 2011; Martin et al., 2006). Additionally, since only one to two high doses of psilocybin can produce immediate and sustained effects, this addresses issues with non-compliance frequently found with standard psychiatric medication (Machado-Vieira et al., 2010).

Recently there has been re-scheduling of some drugs. Cannabis-based medical products, were moved into S2 following media attention surrounding the cases of Billy Caldwell and Alfie Dingley (Deacon, 2020) in addition to substantial research evidence for their therapeutic benefit in a range of conditions, such as treatment of chronic pain in adults (Davies, 2018; Stockings et al., 2020) Indeed, we (JCN, one of the authors of this paper, with the CDPRG-Conservative Drug Policy Reform Group) have prepared a detailed report providing evidence for the therapeutic benefits of psilocybin and presenting the case for rescheduling (Rucker et al., 2020). It is clear that the Government needs to commission an urgent review by the ACMD (Advisory Council on the Misuse of Drugs) into barriers to research cause by psilocybin’s S1 status. This is particularly relevant and urgent as a recent YouGov survey revealed that public attitudes to psilocybin assisted therapy are largely positive and supportive of changes to the law to enable patient access (drugscience.org.uk, 2021). For a recent update on clinical trials of psychedelic medicine, and regulation changes in certain countries to enable patient access, see Aday et al., 2020 and Gonda et al., 2021.

Current research limitations of S1 drugs

However, despite positive effects shown in recent small scale clinical trials for the therapeutic benefit of psilocybin-assisted psychotherapy, so far many clinical trials with these S1 drugs are open-label proof-of-concept designs. Since those involved are aware of the study aims, this increases the likelihood of expectancy effects, which can lead to inflation of the perceived positive outcomes (Muttoni et al., 2019). This is especially likely with psychedelic drugs, in which the individual’s
psychological state can influence their experience (Grinspoon and Bakalar, 1981). Of the few randomised controlled trials which have been conducted, sample sizes remain small and complete blinding of participants and study personnel is difficult due to the visible changes in the state of consciousness produced by these drugs (Rucker et al., 2016). As a result, more methodologically sound research is needed for definitive conclusions to be drawn. However, due to the MDR (2001), there are many practical, financial and bureaucratic barriers to conducting this research (Rucker, 2015). In a survey of members of the UK’s leading psychopharmacology organisation, the British Association for Psychopharmacology (BAP), the most reported barriers to research were found to be the cost of S1 CD licenses, storage and security requirements, transportation difficulties, and penalties for not adhering to the guidelines (Freeman et al., 2018).

The case for qualitative research to understand researchers’ experiences

Whilst Freeman et al.’s (2018) study provides a brief overview of the issues hindering research with S1 drugs, to fully understand what the barriers are, in-depth qualitative research is required (Bryman, 2016) in order to compare the experiences of S1 researchers to those who conduct research with CDs in less restricted schedules, S2–S5.

A theoretical framework that may help advance our understanding of the relationship between these two groups is positioning theory (Harré and van Langenhove, 1999). Positioning theory maintains that individuals situate themselves and others in the world based on established practices, assumptions and components of language. Positioning theory maintains that each action, movement or speech is a socially meaningful performance which reveals knowledge regarding the positioning structures (Harré and Moghaddam, 2003). As a result, positioning theory provides a useful basis to help understand the positions of individuals through examination of spoken narratives (Slocum-Bradley, 2008). The utility of positioning theory as an explanatory framework is clear from a number of studies (Phillips and Hayes, 2008; Ritchie and Rigano, 2001; Slocum-Bradley, 2008), in relation to both an individual and inter-group level of analysis (Liebling and Arnold, 2004; Sargeant et al., 2016). As a result, positioning theory (Harré and van Langenhove, 1999) is a useful tool in developing a richer understanding of researchers’ experiences with the restrictions to S1 drug research.

Study aims

The overall aim of the study is to explore the barriers (and possible facilitators) associated with conducting S1 research by using positioning theory (Harré and van Langenhove, 1999) to compare the experiences of S1 researchers with the experiences of those who do research with other controlled drugs (CDs). In so doing, it is hoped this work will contribute to the evidence required by Government to request the ACMD to review the position of S1 drugs, particularly psychedelics, in view of their clinical potential and the urgent need to conduct further research to realise this potential.

Method

Design

A qualitative approach was taken to build upon the survey conducted by Freeman et al. (2018) and to collect in-depth data regarding participants’ experiences (Bryman, 2016).

Materials

Semi-structured interviews were developed to capture participants’ unique experiences of CD research. Questions were developed based on the survey questions and responses in Freeman et al.’s (2018) study. Interview questions explored the type of research that participants conduct and the necessary arrangements for this research, in addition to their personal views on the scheduling of drugs according to the MDR (2001). Depending on which group participants belonged to, questions were adapted slightly to account for differences in experiences; S1 researchers were asked about complications arising from current UK drug laws, whilst those who conduct other types of CD research were asked about factors preventing them from conducting S1 research. To explore how participants might differ from the other group in terms of their experiences we incorporated positioning theory (Harré and van Langenhove, 1999), asking, for example, ‘Why do you continue with this type of research when others might be put off by the restrictions of S1?’

The first draft of the interview was piloted with a S1 researcher. The transcript of the interview was reviewed, and improvements were made to the interview schedule to further increase the depth of the data. These improvements included the addition of prompts and rewording of questions to give participants more opportunity to express their perspectives and experiences. The interview schedule continued to develop as the interviews progressed to incorporate new areas of interest presented by participants.

Participants

Purposive and snowball sampling were used, allowing for selection of two different groups of participants with different research experiences, in accordance with a positioning theory framework (Harré and van Langenhove, 1999). Seventeen researchers were approached to take part. Of
these researchers, four did not reply and one declined to take part due to a change in research focus. A total of eight participants involved in S1 research took part. These participants included preclinical animal researchers, clinicians, clinical psychologists and pharmacists working on S1 drug trials. Four participants took part who could have undertaken S1 research, as it is within their research area, but do not. These participants included individuals who conduct research with drugs in lower schedules (such as S2) and lecturers in psychopharmacology.

Procedure

Participants were initially approached by JCN (one of the authors). If participants agreed to take part, they were emailed with further details regarding the study. Participants gave informed, written consent prior to the interview. Semi-structured interviews were conducted in March–June 2020, lasting approximately 24 min and were carried out over the phone or using video conference technology. The interviews were audio-recorded using an encrypted Dictaphone and transcribed verbatim. All participants were given an ID number, and any personally identifiable information (names, locations, job titles) was removed from the transcripts to ensure confidentiality.

Ethics

Ethical approval was granted by the (University of Manchester) Research Ethics Committee (ref: 2020-8465-12822, January 01, 2020).

Data analysis

Discourse analysis was used for studying language in relation to its social context (Starks and Trinidad, 2007). This analysis complements a positioning theory framework (Harré and van Langenhove, 1999) in maintaining that knowledge and meaning of positioning structures can be revealed through examination of spoken or written narratives (Kayi-Aydar, 2018). This process first included familiarisation with the transcripts, followed by free coding of the data using NVivo 12 software. Codes were then returned to, and revised, to consider how positioning is signified through language use. Subsequently, these codes were clustered into seven themes for each of the respective groups, which were then collapsed into five overarching themes. These themes were reflected upon to gain a deeper understanding of participants experiences and roles within research. Finally, names were given to the themes based on the aspect of positioning they relate most closely to, and the report was generated.

To ensure external and internal validity, two coded transcripts were reviewed by CL (one of the authors). It was advised that the codes should be further unpicked to access a deeper level of understanding. The two transcripts were then recoded and reviewed for a second time by CL. It was concluded that the codes and themes were appropriate based on the data. This same level of coding was then applied to the remaining transcripts (see Appendix A for all themes, subthemes and codes).

Reflexivity

It is possible that personal opinions towards the MDR (2001) may have influenced wording of questions and the way in which the interview was conducted. For example, since the study was designed to provide evidence to enable a review of current drug legislation, there may have been an over emphasis on exploring participants’ negative experiences of S1 research and a disregard for more positive experiences. Additionally, since it was expected that participants would have had suboptimal experiences with S1 research, this may have been reflected in the questions (see Appendix A). To try and reduce the impact of such opinions and expectations, participants were generally given neutral responses during the interview, showing no judgement, agreement, or otherwise. Nonetheless, it must be acknowledged that these factors could have biased the trajectory of the interview.

Results

Four themes were identified that related to researchers’ experiences, three themes clearly differentiated researchers and their positions (differential burden of duties, the importance of privileges, and motivations), and one theme showed solidarity between the groups (solidarity of researchers against others). Table 1 shows the four themes and the codes which generated these themes.

Differential burden of duties

S1 researchers had to undertake significantly more duties than did the other CD researchers, especially in relation to requirements around obtaining and maintaining a Home Office license. That is not to say that other CD researchers did not have duties, for example, secure storage of drugs and the requirement to complete a CD register. However, for S2 drugs to be used for medical reasons, many of the burdensome duties associated with S1 were not necessary.

Most participants in both groups talked about how this differential distribution of duties acted as a burden for S1 researchers. For example, Home Office licenses were reported to be associated with time-consuming application processes, which often resulted in delays starting research; these delays were considered especially problematic given the desire for research to be published at the time in which it is most scientifically valuable. S1 researchers talked about this application process in-depth, with a participant commenting that it was “bureaucratically like
wading through treacle” (participant 1), a simile used to suggest that these duties were unnecessarily troublesome and time-consuming. Likewise, another participant, participant 7, stated: “there are so many hoops to jump through, even to do this [S1] research, you know the practicalities, it becomes very expensive and difficult”. Here, the metaphor of jumping through hoops again reinforces this idea that S1 researchers must go through a series of complicated tasks, implying a burden of time, energy and financial resources.

The discourse used to describe the perceived burden of S1 duties differed slightly between the groups. Participants in both groups referred to the duties for S1 research as “barriers”, stating that these had either entirely prevented them from conducting the research, or had posed a significant threat to completion. However, S1 researchers often used this term interchangeably with “hurdle”, whereas the other CD researchers did not. Unlike a “barrier”, a “hurdle” was viewed more as an obstacle that could be overcome with hard work. Additionally, due to its connotations with completing a race, use of this term may suggest that the researchers were proud of their ability to complete these duties, since this is what differentiates them from others. These different choices of expression between the two groups may be reflective of the way in which they perceive these duties, and thus how they position themselves as researchers.

Despite these differences, both groups of researchers used similar adjectives to describe the process involved in other types of CD research, such as “easy”, “cheap”,

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**Table 1.** Subcodes and codes used to develop the four themes.

| Themes                      | Codes | Subcodes                                                                 |
|-----------------------------|-------|--------------------------------------------------------------------------|
| Differential burden of duties | Duties | Duties for S2 research lower                                             |
|                             |       | Duties of animal researchers                                             |
|                             |       | Getting patient off existing medication                                  |
|                             |       | S1 license                                                                |
|                             |       | Purchase and supply                                                       |
|                             |       | Storage and security                                                      |
|                             |       | Transportation                                                             |
|                             |       | Similarities in duties                                                    |
| Responsibilities           |       | For safety                                                                |
|                             |       | More responsibility for S1 researchers                                     |
|                             |       | Social norms                                                              |
|                             |       | To adhere to the law                                                      |
| Burden                     |       | To create change                                                          |
|                             |       | To students (PHD)                                                         |
|                             |       | Unclear about responsibilities                                            |
| The importance of privileges| Privileges | Exclusivity/social status                                                  |
|                             |       | Prior experience                                                          |
| Motivations                | Motivations | High motivation                                                           |
|                            |       | Low motivation                                                            |
| Solidarity of research against others | Researchers vs. politicians | Appropriate scheduling                                                     |
|                             |       | Arbitrary decision                                                        |
| Others lacking understanding|       | Distrust of politicians                                                    |
|                             |       | Need for evidence-base                                                    |
|                             |       | Poor application of scheduling laws                                       |
|                             |       | State-control                                                             |
|                             |       | Fear of unknown                                                           |
|                             |       | Lack of scientific understanding                                          |
|                             |       | Lack of understanding about scheduling                                    |
|                             |       | Stigma                                                                    |
“straight-forward”, and “not that complicated”, with participant 4 stating that, compared to S1 research, there was “no hurdle”. Furthermore, most participants believed that the controls and regulations for S2 drugs would be sufficient and appropriate for S1 drugs too.

Motivations

Motivation of the participant was a key intrinsic factor which acted to facilitate S1 research, despite the differential burden of duties. What motivated S1 researchers differed in accordance with the type of research being conducted. For example, clinical psychologists were generally motivated to conduct S1 research to help individuals with mental health disorders, whereas animal researchers were concerned with conducting research to advance scientific discoveries and protect others from harm. Many participants in both groups acknowledged that due to S1 research being a “high energy sort of thing to try and access” (participant 3), individuals were only in the position to undertake S1 research when their motivation was sufficient to justify the perceived burden. The importance of motivation was explained by a S1 animal researcher:

Why have we done it [S1 research] now? We’ve done it now because the motivation outweighs the hurdle, because we are now in a situation where depression research and psychedelics are so much of a topic that it needs to be done, that it would be crazy for me… it was just like I need to do it (Participant 4)

Equally, if participants were not motivated to conduct S1 research, then this acted as a barrier to conducting research. This was demonstrated by a non-S1 researcher who, despite a keen interest in working with cannabinoids, stated: “it’s not worth the effort for that, and it seems crazy” (participant 6). It is important to note how both participants referred to the opposite action as “crazy”, a term used to refer to someone or thing which is different or abnormal; this may suggest that S1 researchers and other types of CD researchers both perceive themselves as distinguished groups.

Differences in levels of motivation within the non-S1 group may be linked to other intrinsic factors, with some participants possessing more determination and resilience. This was the case for a non-S1 researcher discouraged from doing S1 research by their supervisor:

I kind of got to an annoying point where I was super motivated to sort of understand the problem [barriers to S1 research] and try and figure out how to get around it, and my supervisor wouldn’t actually tell me what the problems were (Participant 3)

Here, the participant was compelled to take their own steps to overcome adversity in their environment, which may have acted as a facilitating factor to research.

However, it is evident that, in this case, it was not enough for the researcher to be motivated and proactive, but others working on the project also had to be equally as motivated. This highlights the importance of a collaborative effort in S1 research, in which all individuals must be equally as driven and willing to work together. As a result, it is important to note that intrinsic factors alone are not always enough to facilitate S1 research, and that external factors may play a role.

The importance of privileges

The importance of privileges for example, status, prior experience, facilities and infrastructure, and financial and social support, in facilitating S1 research was acknowledged by most participants in both groups. Those possessing these privileges were perceived as more able to make voluntary choices regarding work (demonstrating high work volition). Since positioning is relational, non-S1 researchers were recognised as lacking in privileges, acting as a barrier to S1 research. In this way, unlike the two previous themes, external factors can be seen to play a determining role in positioning, as opposed to the individuals positioning themselves.

In some cases, privilege was conceptualised in the form of status. This status often resulted from the person or university having had prior experience with conducting S1 research or expertise in this area, which the researchers acknowledged provided them with the knowledge and resources necessary to continue with this type of work. This was evident with participant 9 whose background with opioids led to a natural progression into psychedelic research:

I’m fortunate that I’ve been working in [research area]… I’ve been used to working with controlled drugs… I think if you look at the massive hurdle there is if you’re coming at it fresh, and you see all these things that you’ve got to achieve, it would be, it’s a massive barrier. (Participant 9)

In other cases, privilege was conceptualised in the form of facilities or funding. Funding was regarded as essential, due to the high cost associated with S1 research. However, funding was not easy to obtain, and many S1 participants described a ‘catch 22’ situation in which they could not apply for funding before knowing that the drug could be obtained, yet the drug could not be obtained without funding. These difficulties with financial support were especially true for those non-S1 researchers without prior experience:

it’s only very very very select people that have the potential to do that [S1 research], the funding and the, you know and the work force. It’s kind of like so many
barriers have been put up that you have to be a very specific few, you have to be particularly famous and have, you know, loads of grants and loads of philanthropist behind you, that are willing to chuck millions at you, and it’s such a kind of unavailable thing (Participant 3)

Here, S1 researchers are presented as a ‘closed loop’ of individuals which is hard to infiltrate, regardless of levels of motivation. Repetition of ‘very’ and use of the hyperbole ‘millions’ highlights the participant’s feelings of frustration towards this system, which distinguishes non-S1 researchers from S1 researchers based on whether they have funding or not. Frustration amongst non-S1 researchers was often coupled with a sense of helplessness, whereby participants presented with a resigned acceptance of their lack of power in conducting research of this sort. This gives the impression that non-S1 researchers have been relegated to a less powerful position within the research community based on their access to financial support.

Finally, both S1 and non-S1 researchers also described social support as a privilege which acted to facilitate research. Social support was often from ethics committees and suppliers, in addition to others working within the field who could provide advice about the peculiarities of S1 research. This was the case for participant 11 (a S1 researcher): “We had his help actually, his guiding hand in navigating the system, which was vital”. Whilst both groups recognised the importance of these privileges, highlighted by use of terms such as “need” and “vital” across interviews, the two groups are distinguished by the tone of their acknowledgement. For example, in contrast to the frustration demonstrated by non-S1 researchers, S1 researchers presented with a sense of gratitude and thankfulness.

**Solidarity of researchers against others**

Researchers did not always position themselves as two separate groups, they demonstrated shared beliefs surrounding drug scheduling laws, described by researchers in both groups as arbitrary, with a basis in politics rather than science (as outlined in Nutt et al.’s 2010 MCDA research). Participants generally did not perceive S1 drugs to be dangerous, and instead highlighted their potential therapeutic benefits for treating individuals with mental health disorders. Participants discussed how drugs in lower schedules (such as opioids and cocaine) were associated with greater misuse than several S1 drugs. To demonstrate these common beliefs, a range of similar negative adjectives were used by both groups of researchers to describe the scheduling laws, such as “pointless”, “inappropriate”, “crazy”, and “ridiculous”. These views were illustrated by an animal researcher doing work with psychedelics:

> it’s historical. It’s a complete waste of time. I mean the drugs that we’re talking about are no more dangerous… in fact they’re probably less dangerous, so it’s all down to this fairly arbitrary scheduling process that involves whether it’s a medical, it has a medical use or not. (Participant 4)

Participants often presented these complaints in conjunction with a desire for an “evidence-based” approach, highlighting their dissatisfaction with the current scheduling system. The current scheduling system was suggested to result in a “chicken and egg situation” (participant 8); scheduling laws could not be changed without evidence for the medical value of S1 drugs, yet research into the medical value of S1 drugs could not be conducted due to restrictions imposed by scheduling laws. As a result of this dissatisfaction, most participants displayed distrust towards Government and politicians responsible for reinforcement of such laws, believing they would not change drug scheduling laws in accordance with increases in scientific evidence, due to a fear of losing votes or becoming unpopular. This distrust was shown by a non-S1 researcher who previously did work with adenosine:

> they won’t change because it’s too hot potato, it’s like, it’s why David Nutt, who’s, you know, resigned as the key government officer working on the compounds, because whatever we say they [the government] just ignore, it’s politics, it’s not science (Participant 6)

Although participant 6 was not a S1 researcher, they have used the collective noun of ‘we’ to group themselves with individuals in this category when positioning themselves against the government. The comparison of “they” and “us”, creates a sense of solidarity amongst the two groups of researchers, in addition to disparity between researchers and those in the government.

Researchers also demonstrated a sense of collective identity when comparing themselves to the public; this was based on their superiority of knowledge regarding S1 drugs. For example, participant 5 stated: “people seem to think that a drug not in medicine means that it is dangerous”, suggesting that they believe others are lacking in understanding, or perhaps willing to accept this information as true. Use of the noun “people”, a collective term encompassing everyone, suggests that this is a widespread issue. However, the participant has not included themselves in this group, suggesting again that researchers see themselves as separate from others.

This lack of understanding from others often led to stigma against CD researchers. In some cases, this stigma from others was overt:

> they [S1 drugs] are demonised in our legislature and in the media as being dangerous in some way and therefore if you are wanting to work with them you are labelled with that
Here, the stigma is not just against those currently working with S1 drugs, but also those who ‘wanting to work’ with these drugs, suggesting that the public views anyone expressing interest in this field as a collective group. In this way, the collective identity of the researchers can be seen to determine their personal identity. However, stigma was more commonly described by researchers as covert. This covert stigma included acts such as discrimination from ethics committees and encouragement from academic supervisors to conduct “less controversial” projects, both of which contributed to act as barriers to S1 research. S1 participants reported having to be transparent and engaged with others working on the research team to a greater extent (to allay any existing anxieties).

However, it is important to note that stigma was not experienced by all participants, and S1 researchers were disproportionately affected. For some S1 researchers, privileges such as social support acted as a buffer to stigma, helping them to deal with the associated stress and adversity. This was the case for participant 2, a pharmacist working on a psilocybin trial for treatment-resistant depression: “the trust itself I think is seen in a positive light doing that research rather than any stigma”.

**Discussion**

The current study was designed to explore the way in which S1 researchers and other types of CD researchers position themselves and how this impacts their experiences, in addition to the barriers and facilitators to undertaking S1 research. Interviews revealed that, to some extent, S1 researchers and other CD researchers positioned themselves as two distinct groups, with the distinction based on S1 researchers having a greater burden of duties. This greater burden of duties acted as a barrier to non-S1 researchers, whilst S1 researchers were better able to deal with this burden due to having high levels of motivation and more privileges (both of which acted to facilitate S1 research). However, there was some solidarity between the two groups, which was especially prominent when the researchers positioned themselves against others, such as government officials or those who possess less scientific knowledge. Both the government and the public acted as barriers to S1 research, since government officials prevented changes to legislation which might make S1 research easier, and those lacking scientific understanding (including non-drug researching academics and university staff) were often discriminatory to S1 researchers, leading to difficulties in getting S1 research projects started.

The first theme, *differential burden of duties*, refers to the greater number of duties necessary for S1 research than for other types of CD research (e.g., S2). These additional duties for S1 research, such as obtaining CD licences from the Home Office, maintaining security and external audits, were perceived as troublesome and difficult by both S1 researchers and non-S1 researchers, acting as barriers to research. These findings are consistent with those from Freeman et al. (2018) who, in a survey with members of the BAP, identified barriers to S1 research to be, cost of the S1 CD licenses, storage and security requirements, transportation difficulties, and penalties for not adhering to guidelines. As with the current study, these duties were associated with burdens of time, energy and financial resources. However, the current study extends upon the findings of Freeman et al. (2018) through comparing the experiences of S1 researchers to a second group (non-S1 researchers). As a result, more in-depth data was able to be generated regarding the impact of these barriers and how participants interpreted and responded to them. For example, the language used by participants suggested that S1 researchers viewed these barriers as manageable, whilst non-S1 researchers did not.

One of the factors which distinguished S1 researchers from non-S1 researchers in terms of how these barriers were responded to was motivation of the participant, with S1 researchers generally having higher levels of motivations to engage in S1 research than other types of CD researchers. This lack of motivation in non-S1 researchers was often due to these researchers viewing the S1 research process as unnecessarily burdensome, believing that the work would not go anywhere particularly ‘high impact’, and prevented them from engaging in behaviours which would have facilitated S1 research (such as investing time and energy into completing duties). These findings provide support for expectancy theory (Vroom, 1964), which maintains that individuals evaluate and choose work behaviours based on what they perceive will lead to the best and most valuable work-related outcomes. In accordance with expectancy theory, the current study suggests that the energy and motivation invested by the researchers was dependent on the extent to which they believed engaging in and completing S1 research would lead to valued outcomes (e.g., publishing a high impact paper).

The reason for low work impact expectancy relative to burden amongst non-S1 researchers was proposed by participants in both groups to be due to a lack of privileges (highlighting the importance of privileges). These findings provide support for the psychology of working theory (PWT; Duffy et al., 2016), which maintains that contextual and structural factors, such as economic constraints, work volition and marginalisation predict decent work; this relationship is proposed to be moderated by several other psychological and economic variables, including proactive personality and social support. In accordance with PWT, the current study found that non-S1 researchers without funding had fewer opportunities to engage in S1 research.
than those with funding, suggesting that economic constraints of individuals and institutions prevented work with S1 drugs.

Additionally, as with the PWT, lack of funding and facilities were related to low work volition, with participants lacking these privileges feeling less able to make voluntary decisions over the type of research they could conduct. The current study also found social support to moderate the relationship between economic factors and securing decent work, with those receiving advice from others more able to conduct S1 research. However, in contrast to the PWT, the current study did not find having a proactive personality sufficient to moderate the relationship between economic constraints and decent work, suggesting that some moderating factors may be more valuable than others in predicting S1 research.

Whilst S1 researchers positioned themselves against other types of CD researchers in some respects, the two groups could be seen to take on a collective identity in their positioning against others. This reinforces the idea that, in the real world, individuals adopt multiple positions which are dynamic and change in accordance with the social context (Harré and Moghaddam, 2003). It is likely that the researchers simultaneously adopted multiple positions in order to help them navigate and make sense of the questions asked by the interviewer (Andreouli, 2010). Furthermore, it is important to note that whilst the researchers saw themselves as distinct from these two groups in terms of their beliefs, participants also described how this view was reciprocated. For example, the public were perceived as viewing themselves as separate from CD researchers, believing the researchers were ‘crazy’ for wanting to work with these dangerous substances. This highlights the idea that an individual’s position is not only determined by the individual themselves, but also how by they are viewed by others, allowing them to take on the role of both the positioner and the one being positioned at the same time (Duveen, 1996; Harré and Moghaddam, 2003).

The use of positioning theory (Harré and van Langenhove, 1999) in this study allows us to take into consideration the social dynamics positioning takes place in, the participants’ personal attributes, and the importance of discursive processes (Harré et al., 2009). It allows for the direct comparison of two different groups of researchers, which helps reveal facilitating factors related to S1 research. This differs from previous work into S1 research, such as Freeman et al., 2018, which focuses predominately on barriers to S1 research alone. In addition, participants were from several different universities across the UK and therefore represent a diverse range of experiences and opinions. Therefore, this may suggest that the findings are a valid reflection of the views and experiences of S1 researchers. However, most participants were initially approached by JCN, or through snowball sampling. Since individuals tend to affiliate with like-minded people (McPherson, Smith-Lovin and Cook, 2001), it is possible that this may have biased the sample, causing the selected participants to all hold similar views. Additionally, there were more participants in the S1 research group. Since new topics continued to come up, we may not have reached data saturation for the non-S1 researchers.

These findings, coupled with the increasing amount of research in support of S1 drugs for treating mental health disorders and public support for psilocybin assisted therapy (dos Santos et al., 2016; Rucker et al., 2016), suggest that Government should take reasonable steps to make the S1 research process smoother and more accessible. It is hoped that the current study will contribute to a wider project providing Government with the evidence required to review drug legislation for research and medical purposes. Table 2 highlights the key recommendations from this study and the supporting evidence from the results.

### Table 2. Key recommendations and evidence from the results to support the recommendation.

| Key Recommendations | Evidence |
|---------------------|----------|
| Reduce the barriers to researching S1 substances so as to be in line with the regulations controlling those in S2. | Both S1 researchers and non-S1 researchers perceived S1 research as a burden, which prevented many from conducting S1 research. |
| Commission the ACMD to do an urgent review into current scheduling of substances which appear to have potential medical application, such as psilocybin (in order to change policy to re-schedule these to enable research). | Many people were discriminatory towards S1 research, such as ethics committees not wanting to accept projects with S1 drugs due to believing they are dangerous. This acted as a barrier to S1 research. |
| Government could distribute resources such as funding, infrastructure and social support more evenly across CD research projects. | Privileges such as funding, infrastructure, and social support were found to facilitate S1 research, with those lacking these privileges less able to conduct S1 research. |
| Knowledge of the way S1 and non-S1 researchers position themselves opens up several different avenues of inquiry. Future research may act to explore how researchers’ positioning may shift in accordance with changes in moderating factors, such as economic conditions. | Non-S1 researchers without funding had fewer opportunities to engage in S1 research than those with funding, suggesting that economic constraints prevented work with S1 drugs. |
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Author contributions
CL supervised the data analysis and development of the initial manuscript. JCN conceived the idea for this study. CL, JCN and AH planned the study. AH and CL performed the data analysis. JCN assisted with participant recruitment. AKS provided ideas and input to preparation of the manuscript.
All authors reviewed and agreed the final manuscript.

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Appendix 1

Interview topic guide: Understanding researchers’ experiences of controlled drug research

1. Introduction and consent (5 min).
   - Introduce self
   - Forensic and Mental Health MSc student from University of Manchester.
   - Remind about the project and purpose of interview [Info sheet content]:
     - Overall objectives of the project.
     - Remind/explain the interview will take 45–60 min.
     - Remind that all data is confidential (and the limits of this).
     - Ask if they have any questions.

2. Interview (45–60 min).
   - ‘Describe the type of research that you do?’
     • If they do conduct controlled drug research:
       - ‘Tell me about the arrangements for your research using controlled drugs, to get the license?’
       - (e.g. ‘renewal fees, costs, checks, staffing, storage, police checks, penalties?’)
     • If they do not conduct Schedule 1 drug research:
       - ‘What do you know about the licensing requirements for Schedule 1 drug research?’
       - ‘How do you know this?’ (e.g. ‘word of mouth’/’other researchers’/’first-hand experience?’).
     • If they do not conduct Schedule 1 research:
       - ‘Why do you not conduct Schedule 1 research?’
       - ‘What factors are stopping you?’
       - ‘Why do you think that other people are able to?’
     • For those who previously conducted Schedule 1 research and now do not:
       - ‘What factors stopped you from conducting Schedule 1 research?’
       - ‘What might the reasons be why others have continued with Schedule 1 research when you have not?’
     • ‘What complications have you experienced due to scheduling laws?’
       - ‘How have these been dealt with?’ (e.g. may be due to problems with GPs having to be on board in order for patients to off their antidepressants before the trial).
     • If they conduct Schedule 1 drug research:
       - ‘Why do you continue with this kind of research when others do it and then stop/might be put off by the restrictions?’
       - ‘Why are they different?’
     • ‘How has researching with controlled drugs affected applications for funding and ethical approval?’
     • ‘Have you experienced pressure from your faculty/university management to avoid controversy by researching with drugs?’
       - If yes: ‘What did this entail?’
       - ‘What are your views on the scheduling of drugs?’
       - If too strict: ‘What does it prevent?’ (e.g. ‘research’?).
       - If appropriate: ‘Why?’
     • ‘If the restrictions were lifted for a time what would you see as the benefits?’
       - ‘More research?’
       - ‘Patient benefits?’
       - ‘Increased scientific knowledge?’
     • ‘What might the negatives be if drug scheduling laws were changed?’
       - ‘Public opinion?’
       - ‘Harms to patients?’
     • ‘Do you think the drug laws should be changed?’
       - If yes: ‘What are your views on how to persuade the government to change drug scheduling laws?’
       - If no: ‘Why not?’
       - What would an idealised system of regulation look like for you?
3. Close (5 min).
   - Is that everything?
   - Thank: for their time.
   - Check: if they have any questions.

Additional notes:

   - If they do both Schedule 1 and Schedule 2 research:
     - ‘What are some of the main differences between Schedule 1 and Schedule 2 research in terms of the necessary arrangements?’
     - ‘Why do you think these differences exist?’
     - ‘Are they necessary?’