Probing the functional magnetic resonance imaging response to psilocybin in functional neurological disorder (PsiFUND)

Participant information sheet: Main Document

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PARTICIPANT INFORMATION SHEET

Probing the functional magnetic resonance imaging response to psilocybin in functional neurological disorder (PsiFUND)

You are being invited to take part in a research study called the 'Probing the functional magnetic resonance imaging response to psilocybin in functional neurological disorder (PsiFUND)'. This study is being undertaken as part of a PhD project. You do not have to take part and if you decide not to your care and treatment will not be affected in any way. Before you decide, it is important for you to understand why the research is being done, what your participation will involve and what the potential benefits and risks to you are. Please take time to read the following information and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. You can take as much time as you like to decide. Part 1 tells you the purpose of this study and what will happen if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of this study?

The purpose of this study is to determine whether the substance called psilocybin changes the way that parts of the brain talk to each other, in functional neurological disorder.

What is the background to this study?

Functional neurological disorder (FND) is a common problem and some people do not get better despite usual medical and psychological treatments. We do not yet fully understand why people develop FND, however there is emerging evidence that there are brain network changes which we can see on brain scans.

Psilocybin is the active ingredient of so-called 'magic' mushrooms. Psilocybin mushrooms have been used in ceremonial or healing rituals stretching back thousands of years. There are now dozens of clinical trials of psilocybin underway for brain disorders ranging from chronic headaches to treatment-resistant depression.

Evidence from studies and case reports of psilocybin in people with FND from the 20th century indicated that the substance is well tolerated. The data is not yet good enough for us to say with any certainty that people's symptoms improved in these cases, but there was limited evidence for worsening of symptoms.

This study will test whether the brain networks we think might be involved in FND can be changed by the administration of a single dose of psilocybin given with psychological support in a hospital

setting. Brain networks are parts of the brain which communicate with each other in a coordinated fashion, and this communication is thought to be altered in FND. Every person who is enrolled in the study will receive a single active dose. Both you and the study team will be aware that you are receiving an active dose.

We are looking for 24 participants aged 25-60 years with functional neurological disorder that hasn't improved despite the usual treatments to take part in this study.

Who is eligible to take part?

We are looking for people aged 25-60 years who are able to engage with face-to-face psychological support (undertaken in English without a translator). To be eligible you need to be currently suffering from functional neurological disorder and have not significantly improved despite at least one standard treatment, such as physiotherapy or cognitive behaviour therapy. You may be suffering from different types of functional neurological symptoms or subtypes, including functional seizures or functional motor disorders. We will not be recruiting those with purely sensory or cognitive subtypes of FND. You must have active symptoms which are at least moderately severe: this will be confirmed by an assessment by a doctor if you are invited to screening. You will also need to be able to tolerate two functional MRI scans (please see 'MRI scans' section below), which can be loud and can make some people feel claustrophobic. There are other reasons why you might not be suitable for an MRI scan, such as the presence of metal in the body.

There are some reasons why you might not be eligible for this study even if you fit the above criteria. You won't be eligible if you or an immediate family member has a history of severe mental illness; this does not include mild or moderate anxiety and depression but does include things like bipolar affective disorder, substance use disorders, psychosis, persistent suicidal thoughts, or personality disorders. We will also not be able to recruit you if you have some neurological syndromes like dementia or learning disabilities. There are also some other physical health conditions, such as severe heart disease, which would mean you would not be suitable for inclusion. The reasons we will not be including people with any of these factors is because psilocybin is still an experimental drug with somewhat unpredictable individual psychological effects, and we do not want to destabilise anyone who may have a pre-existing vulnerability. As is the case with many research studies, we will not be able to enrol you if you are able to get pregnant and you are not using contraception, or if you are currently pregnant or breastfeeding. Finally, we will not enrol you if you have used psychedelic substances more than two times in the past year.

In order to confirm your eligibility, we will need to meet you face to face a number of times, perform some routine blood tests and an ECG and get to know you and your current situation. We will also need your GP to provide us with a copy of your medical history, which will include a summary of

medical problems over your lifetime. You must be registered with a UK GP for the duration of the study.

It's important to emphasise that many people, for various medical or personal reasons, turn out not to be eligible for the study. Whilst we do not want to discourage you volunteering, please take the time to read this information sheet fully so you can decide if this study is right for you. Please feel free to ask us any questions if anything is not clear.

You can be based anywhere in the UK to take part in the study, and we will be able to reimburse you for reasonable travel expenses. Nevertheless, please note we have insufficient funding to provide payment or reimbursements for your time.

Do I have to take part?

No, you do not have to take part. If you decide not to take part your care and treatment will not be affected. If you do decide to take part, you can withdraw at any time.

What will happen to me if I take part?

We will send you a link to a short survey you can fill out online. This survey will ask you some basic information about yourself and your FND and should take no longer than 20 minutes to complete. The survey will be hosted by the online software Qualtrics; this is a secure software which has been approved for use by KCL. For a link to the Qualtrics privacy notice, please visit https://www.qualtrics.com/privacy-statement/.

If we think you may be suitable from the survey, we will invite you to a meeting where we will talk to you about your history and current circumstances in depth to help us decide. This first meeting will take place online using Microsoft Teams.

All subsequent visits will take place at the NIHR/Wellcome King's Clinical Research Facility (CRF), Cheyne Wing, King's College Hospital, Denmark Hill, London, SE5 9RS OR The Centre for Mental Health Research and Innovation (CMHRI), 5 Windsor Walk, Denmark Hill, SE5 8BB.

If we think that you are suitable at this point, then you will be invited to a face-to-face visit at the CRF or CMHRI, which is called the Screening Visit. During this visit, you will need to:

- Have a blood sample: for routine laboratory tests,
- Provide a urine sample test: for routine analysis of your urine, to screen for drug use, and for a pregnancy test (if relevant),
- Undergo a heart tracing (ECG),
- Consent for us to contact your GP or healthcare team to ask them to share the information they hold about you with us.

This visit will last approximately 4-6 hours.

A doctor will then go through this information and make a decision with you about your suitability for the study. This decision is taken by a panel which consists of the study doctors and psychological therapists which meets each week during the study period. If you are enrolled into the study we will contact you to arrange a schedule of visits. We will also need to notify your GP that you are enrolled in this study. This notification of enrolment may stay in your GP records.

If you are currently taking some medications (including antidepressants and some pain medications) then we will help you to stop taking them, because otherwise psilocybin might not have an effect on you. A doctor will oversee the withdrawal of your medication.

We will ask you to notify us of a 'support person' who will help you through the trial. This can be a friend, family member, carer, colleague, or anyone else who you trust. We will briefly liaise with the support person to ensure they know what will happen with you throughout the trial. We suggest that the support person is someone who can be there to support you, psychologically and emotionally, throughout the trial process, and who is also able to support you with practical things, such as arranging pickup at the end of the dosing day.

We will ask your carer or support person to contact us if they think that your physical or mental health is deteriorating. If this happens, then we may recommend that you restart your previous treatment or another treatment. It will be the primary responsibility of the study team to monitor your health, not your caregiver or support person, but we may ask them to provide information which may help us understand your condition better.

If you are enrolled in the study, we will see you in the research facility each week to review you and how you are getting on. These visits will include several surveys and questionnaires, which vary slightly between the visits. These visits will usually take around two hours in total. The session with the fMRI session will take around six hours.

Before you receive the psilocybin, you will be introduced to two people who will be your therapist and co-therapist on the day when you receive the psilocybin. Both will have experience of accompanying people who take psilocybin in medical settings, and at least one will be a psychotherapist or a psychiatrist. You will have some time to get to know each other before you receive the psilocybin, and it is important that you feel a sense of trust between you. If you are struggling with this, then please tell us. These therapists, who are professionally trained and accredited, will talk with you to help you understand how psilocybin might affect you. We will give you details of the study website that will contain information about the study, educational materials about psilocybin, contact details for the study team, and frequently asked questions.

You will meet with your lead psychotherapist or psychiatrist for at least three hours on at least two separate occasions before your dose, but it could be longer if we decide that you need more time to prepare.

Your final eligibility for the study will not be confirmed until shortly before we plan to give you the study drug. This means that you might be excluded from the study even though you thought you were eligible. This usually happens because new information becomes available that we didn't know before. However, it might happen because we decide that it isn't safe for us to give you psilocybin. We can only make this judgement once we have got to know you and you have got to know us. The study team will endeavour to provide you with reasons for you not being eligible, should you wish to know this. Please consider this point carefully. It might mean this study is not right for you.

On the day of your dosing, you will come to a comfortable, quiet room at the NIHR/Wellcome King's Clinical Research Facility, Cheyne Wing, King's College Hospital, Denmark Hill, London, SE5 9RS OR The Centre for Mental Health Research and Innovation, 5 Windsor Walk, Denmark Hill, SE5 8BB. There will be a reclining chair, sofa or bed to lie on and we will give you eye shades and headphones with calming music to help you relax. Food and drink will be available if you need it and there will be a lavatory nearby.

The Dosing Visit and other study visits may be filmed (on a laptop and stored on a secure network via Microsoft Teams) for safety and/or training purposes, however participants will have the option to ask us to switch this off if they feel uncomfortable and non-consent to this aspect will not affect enrolment. Video and audio recordings will be downloaded from the camera and stored on a secure device as soon as is feasible after the recording has been made and will then be deleted from the camera.

The dose will consist of psilocybin capsules to take by mouth with a glass of water. This is manufactured in a laboratory to pharmaceutical standards. Before we give you the capsules you will need to tell us that you agree to stay at the hospital with your companions until the doctor is satisfied that you are safe to leave.

Once you've taken the dose, your therapist and co-therapist will stay with you. A doctor will also be available if necessary. We will encourage you to lie back, relax, listen to the music, and let your mind go where it needs to. Please note that you will not be allowed to bring anyone else with you into the dosing room.

People who have taken psilocybin have told us the experience is like a 'waking dream'. Like a dream, you might experience a wide variety of unusual sensations and feelings (such as feelings of warmth or cold, or changes in the feeling of connection with your body), but none of these experiences are dangerous to you. All these experiences are limited to the short-term psychedelic experience. Psilocybin is not known to be toxic to the body.

If you try to leave the hospital after you have taken the dose, then we will stop you if we think you are under the influence of the dose and leaving would be risky for you or others. We will discuss this

with you when you sign the consent form, but it is important that you think about this carefully, because it might not be right for you.

The effects of the dose usually last about six hours. Usually, the whole day should last until about 17:00, but it could be later. At the end of the dosing session a doctor will decide if you are safe to go home. If we don't think you are safe to go home and it is late, then we may ask you to stay in the hospital overnight. If we think that you are safe to go home, then we ask that a nominated friend or relative (i.e., your support person) pick you up. We will not give you any psilocybin to take home.

The next day, we will ask you to come back. We will ask you about how you have been feeling, if you have had any side effects to the dose and ask you to fill out some more questionnaires. We will help you to understand any difficult experiences you might have had. You can then go home.

We will ask you to come in for further face-to-face meetings with us at 1 week, 3 weeks, 6 weeks, and 3 months after the dosing session. We will ask you about how you have been feeling, if you have had any side effects to the dose and ask you to fill out some more questionnaires. These sessions will take around two hours each. The session with the fMRI session will take around six hours. You can then go home. Your participation in the study will end 3 months after your dosing session.

Below is a table to help you understand the time needed for you to be a participant in this study. We can be flexible within certain limits (usually between 1 and 3 days) about the specific days that you visit, but if you think you are not going to be able to attend more than 1 of the study visits, then please tell us at the first visit. We will pay your travel expenses, but we cannot pay you for the time commitment for the study. The total time commitment for you will be about 36 hours spread over 10 visits over the course of 3-5 months, depending on your particular circumstances.

	Screening & preparation				**Dosing**	**Follow-up**				
Visit number	1	2	3	4	5	6	7	8	9	10
Phase length	1-8 weeks				1 day	3 months				
Visit length (hrs)	4	2	2	6	8	2	6	2	2	2
Location	King's College Hospital, Denmark Hill, London									
Extras				**fMRI**	Dose		**fMRI**, interview			

Table 1: Schedule of Visits.

MRI scans

As part of the study, you will have two MRI scans of your brain. One scan will be before the dosing, and one will be around a week after dosing. You will not have an MRI scan on the dosing day. We will check if you are eligible for the MRI scan at screening day. In some situations, such as if you have

metal in your body, you will not be eligible for the scan and therefore will not be enrolled in the study.

MRI is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body. An MRI scanner is a large tube that contains powerful magnets. You lie inside the tube during the scan. It's important to keep as still as possible during your MRI scan.

The MRI scanner is operated by a radiographer, who is trained in carrying out imaging investigations. You'll be able to talk to the radiographer through an intercom and they'll be able to see you on a television monitor and through the viewing window throughout the scan. At certain times during the scan, the scanner will make loud tapping noises. This is the electric current in the scanner coils being turned on and off. You'll be given earplugs or headphones to wear.

MRIs are painless scans and are one of the safest medical procedures available. You may find it uncomfortable if you have claustrophobia, but most people are able to manage it with support from the radiographer. We will offer you the opportunity to spend some time in a mock scanner prior to your first session which may help you feel more comfortable when it comes to the real scan.

In this study, we will be conducting several different scans within the same session on both of the two occasions. The MRI will take pictures of the structure of the brain, as well as how parts of the brain talk to each other (the function).You will enter the scanner once per session and will remain in there whilst the scans are undertaken. Some of these will involve you lying still with your eyes open. We will also be asking you to undertake a specific task, called Libet's clock test. In this task, you will need to look at a computer screen and watch a ball rotate around a clock. We will ask you to stop the ball and then use a joystick to indicate when you felt the urge to stop the ball. This task has been used in other MRI scanning studies of people with FND in the past.

The MRI scans will be uploaded to the secure clinical system at King's College Hospital where they will be reviewed as standard by a clinical radiologist. You should be aware that there is a possibility that your participation in the study and the study tests may reveal an unexpected result that may have relevance for your physical or mental health. If this happens, we will discuss this with you and, if necessary, inform your GP and arrange appropriate follow-up. In an emergency we will ensure that you are assessed either by our medical and psychiatric team or if more appropriate, in an Accident and Emergency department. The research team will also receive pseudoanonymised versions of the scans for analysis.

Optional interview

If you are suitable for the study, we will ask you whether you would like to take part in an optional interview. You don't have to consent to this to take part in the main study, but if you do it will help us further understand how this intervention might work.

The interview will last 1-2 hours and will focus on your experience of being part of the study, including your experiences during the dosing sessions. It will take place on a visit day after the dosing session. The interviewer will sit one on one with you in a private room and will ask you pre-specified questions such as:

- How did you find the dosing session?
- How would you describe the experience of the dosing session to a friend?
- Were there any changes to your FND symptoms during the dosing?
- What are your thoughts about psychedelics as a possible treatment for FND?

There are no 'right answers' to these questions, and so the interviewer will let you talk for as long or short a period as you feel comfortable. In general, it might take around 60 – 90 minutes to complete, but it could be less.

This interview will be audio (not video) recorded via Microsoft Teams where it will immediately be uploaded to the KCL secure cloud platform. It will later be transcribed into writing by a member of the trial team before the audio file is deleted. Your responses to the interview questions will be anonymised and brought together with responses from others to form 'themes'. Direct quotes may be taken from answers and used in research reports or presentations (particularly in any paper summarising the qualitative interviews) but will be brief and anonymised. We will ask you to consent for direct but anonymised quotes to be shared in any subsequent publications. If you would prefer not to consent to this, it will not affect your enrolment into the study or to the interview.

What will happen to my samples?

As part of the study, you will have blood samples taken from a at Screening. The sample will require no more than 10ml of blood (equivalent to around two teaspoons). The blood samples will be sent to the laboratory at King's College Hospital and will be analysed for routine tests such as kidney and liver function. This is to ensure that you are physically well enough to proceed to dosing. The samples will be destroyed after analysis and will not be kept for future use. It is possible that you may need to provide additional samples if there are any problems with the analyses, however the study team will always inform if this is necessary.

You will also need to provide a urine sample on one or two occasions. At screening, we will ask you for a sample which we will test at the time in the CRF or CMHRI. The sample will then immediately be disposed of and will not be stored. If you are a person of childbearing potential, we will ask you for a second sample of urine to repeat the pregnancy test at the Baseline Visit. Again, this will immediately be destroyed after use.

What are the possible effects of taking psilocybin?

Psilocybin is called a 'psychedelic' drug and it can have a wide range of effects that depend on the individual person and their circumstances, so it's hard to predict how it will affect you personally. Some of psilocybin's effects will be unfamiliar or strange to people who have not experienced them before.

The following effects may, or may not, happen to you.

1. Heightened emotions. Psilocybin can lead to heightened emotions of any kind, from bliss and ecstasy through to anxiety and, more rarely, panic or paranoia.
2. Vivid, dream-like experiences or memories whilst you are awake. This is a bit like day-dreaming.
3. Visual disturbances such as vivid colours, textures, geometric patterns or illusions. Rarely, psilocybin causes visual hallucinations.
4. Changes in the sense of time. Time may seem to be passing slowly, quickly or may seem not to exist at all.
5. Changes in how your body feels. This can range from aches and pains or feeling the need to use the lavatory to tickling/tingling sensations, or hot/cold sensations running through the inside or on the surface of your body.
6. Changes in your 'sense of who you are'. You may feel as though you 'no longer exist', that you have 'died' or been 'reborn'. This is called 'ego-dissolution'.
7. Other experiences that can have a deep personal significance for you (noetic), but which are hard to put into words (ineffable).

Most people feel back to their usual selves about 6-8 hours after taking psilocybin. Sometimes it takes up to 12 hours. We know that psilocybin has completely left the body after 24 hours. Psilocybin is not known to be toxic to the body. Some participants may experience a feeling of queasiness or nausea during the dose, but it is very rare for someone to vomit. The most common after-effects of psilocybin are a feeling of mental 'exhaustion' and a headache. You should get plenty of rest after you have received the dose. You can take simple painkillers like paracetamol for the headache if it is troublesome. Psilocybin is not known to stop you from sleeping.

What are the possible benefits of taking part?

1. You will be helping with clinical research, which may help others in the future.
2. The study drug may induce positive feelings.

What are the possible risks of taking part?

1. Most people who volunteer for this study will, for one reason or another, turn out not to be eligible. Your eligibility for this study will not be confirmed until shortly before the day of dosing and the study team reserve the right not to give you the study drug if they think it is not in your best interests. It could be very disappointing and frustrating for you if you volunteer for this study and then are excluded shortly before dosing. This does not happen often, but please consider this possibility before deciding whether to take part in this study.
2. The study drug may make you feel worse, or may result in other symptoms that you did not have before.
3. Some people who take psilocybin-containing mushrooms in a recreational setting report ongoing disturbance in their vision and unpleasant sensations, emotions or charged memories long after the drug has left the body. We do not know if this will happen when psilocybin is given in a study setting, however it has not happened to anyone in modern studies thus far.
4. We will ask you questions about your life history and current circumstances. This can include personal questions about traumatic events that may be distressing.
5. We will ask you to have blood tests, which may be painful and could lead to bruising or infection where the needle enters your skin.

Safety Database

We want to increase understanding of psilocybin's safety profile. To do this, we are working with a company called COMPASS Pathways, who manufacture the psilocybin and are seeking to collect a consolidated database of safety data from different studies. Safety data we collect as part of the study will be transferred for storage in a secure central database with restricted access, managed by COMPASS Pathways (and their contractor Worldwide Clinical Trials). All data in the database will be anonymised, which means your name will not be associated with it. The data may contain information about your medical history (but only if it is relevant to the safety event that is recorded). The data may be held in this database indefinitely, but you will be able to request to see any data stored in the database relating to your study participation and request for it to be removed.

What happens when the research study finishes?

We will keep in touch with you to let you know the results of the study if you wish and we will organise events to help raise awareness about the results of the study. We will ask for your consent to contact you about other studies in functional neurological disorder or with psilocybin that might interest you.

What about media interest?

Because psilocybin has a colourful history, it is possible that the media may be interested in the study. We will never tell the media that you are involved in the study. However, if the media

approach you then please do not talk to them. Refer them to the Principal Investigator of the study, who is Dr Tim Nicholson.

Isn't psilocybin Illegal?

This study has received all required government approvals. It is legal for you to be given psilocybin in this study. No one who receives psilocybin in this study will be committing a criminal offence.

Nevertheless, psilocybin is currently a Class A prohibited substance in the United Kingdom, and hence any use outside of an approved study or trial is illegal. We do not endorse or encourage the use of psychedelics outside of regulated studies.

Will this study affect my medical insurance?

We suggest checking with your medical insurance provider, if you have this. You should tell them that this is government approved medical research using a single dose of psilocybin or placebo that has been manufactured to 'good manufacturing practice' standards. There is no ongoing medication.

Can the study team stop me from participating in the study?

Yes. The study team and the sponsor of the study can stop your involvement at any time. For example, this may happen because we are concerned for your safety if you continue in the study.

PART 2

What if relevant new information becomes available?

It is possible that whilst performing normal medical checks we may identify a significant problem that you didn't know you had. If this occurs, we will inform you.

Sometimes during a research project, new information becomes available about the study drug. Although unlikely, if this happens, a member of the research team will tell you about it and discuss whether you want to continue in the study. If you decide to continue in the study, you may be asked to sign an updated consent form. If the study is stopped for any other reason, we will tell you why.

What will happen if I don't want to carry on with the study?

If you withdraw from the study, your usual care and treatment will continue as before. We will retain and continue to use any data collected before you withdrew.

How do I get help if I am concerned about anything?

If you have a concern about any part of this study, you should ask to speak with a member of the study team, who will do their best to address your concerns. You should report any adverse events or medical occurrences that you experience whilst in the study to a member of the study team. If you have any medical concerns that cannot wait until you can talk to a member of the team you should dial 111 to talk to NHS direct (24 hours a day), or speak to your GP or secondary mental health

care professional using the information in this sheet to tell them about your participation in the study. In an emergency, you should visit A&E or dial 999.

What if there is a problem?

Any complaint about your experience within the study will be responded to and we will try to address any concerns you have as best we can. Detailed information is given in Part 2 of this document. Please contact Dr Tim Nicholson if you have any complaints about the study. You can also talk to an independent body, such as the Sponsor's Patient Advice and Liaison Service (PALS). Contact PALS on freephone 0800 731 2864 (Option 2) or by email at pals@slam.nhs.uk.

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). King's College London has obtained insurance which provides no-fault compensation i.e. for non-negligent harm, you may be entitled to make a claim for this. If you have any questions about the study, if you want to know your rights as a research volunteer, if you want to tell us about any side effects, or if you want to make a complaint please contact us at PsiFUND@kcl.ac.uk

Will my participation in this study be kept confidential?

Yes, however we need to tell other professionals involved with your care, for example your GP, that you are a part of this study and if any serious concerns arise. Similarly, we will ask them whether they have any concerns about you being in the study. They are bound by the same legal duty of confidentiality as the study team. We will always try to ask for your approval before contacting your GP or other health professional if we have concerns about your safety or welfare. However, it we think that your safety and welfare is seriously at risk then we may not seek your consent beforehand if we think this would introduce unnecessary delay or cause unnecessary risk to yourself or others.

For this study you will need to give us the contact details of a trusted friend or relative who you are happy for us to speak to about your participation in the study. We will speak to this person if we need more information about you, or if we are worried about your safety. We recommend that this person accompany you home after the dosing.

How will we use information about you?

We will need to use information from you, from your medical records, from your named carer or relative (support person) and from your GP for this study. This information will include your name, initials, date of birth, contact details and NHS number. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. At the beginning of the study, you will be allocated a code number that will be used to identify all

the research data we keep about you. Your name, address and other identifiable information will be kept in a separate, secure place, with the code number. This means that it will not be possible to identify you from any research data stored about you.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. Research data collected on paper will be stored securely in files in a locked cupboard, or in a locked office. Electronic research data and audio-visual data will be stored on secure computer servers located in the same country as the study itself. Only members of the clinical or research team or representatives from the Sponsor will have access to your data.

King's College London and the South London and Maudsley NHS Foundation Trust are the co-Sponsors for this study, based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Sponsor organisation will keep identifiable information about you for 10 years after the study has finished or until it is no longer needed for research. After this it will be destroyed, either by shredding (paper) or secure deletion (electronic data).

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You can find out more about how we use your information at:

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to King's College London Data Protection Officer Mr Olenka Cogias, info-compliance@kcl.ac.uk (KCL) or via https://www.slam.nhs.uk/about-us/privacy-and-gdpr

What will happen to the results of the research study?

The results of the study will be published in academic peer-reviewed journals, presented at conferences and discussed at other public events. We will also produce a newsletter summarising the findings of the study which we will send to you and your clinical team. You will not be identified in any report or publication.

Who is organising and funding the research?

The study is organised by the Institute of Psychiatry, Psychology & Neuroscience, King's College London. The sponsors of the study are King's College London and the South London and Maudsley NHS Foundation Trust. Funding is provided by the KCL-Wellcome Mental Health Research for Health

Professionals programme. The psilocybin drug substance is manufactured by Compass Pathways, Ltd. The researchers involved in conducting this study do not receive any financial incentives for including you in this study and do not benefit financially from this study.

Who has reviewed the study?

This research has been reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. We have also sought advice from FND patient representatives in the design and planning of this study.

Names of the study team

Principle Investigator: Dr Tim Nicholson

Lead Investigator: Dr Matt Butler

Contact us:

Email: psifund@kcl.ac.uk