

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

Participant information sheet: Schedule of Events

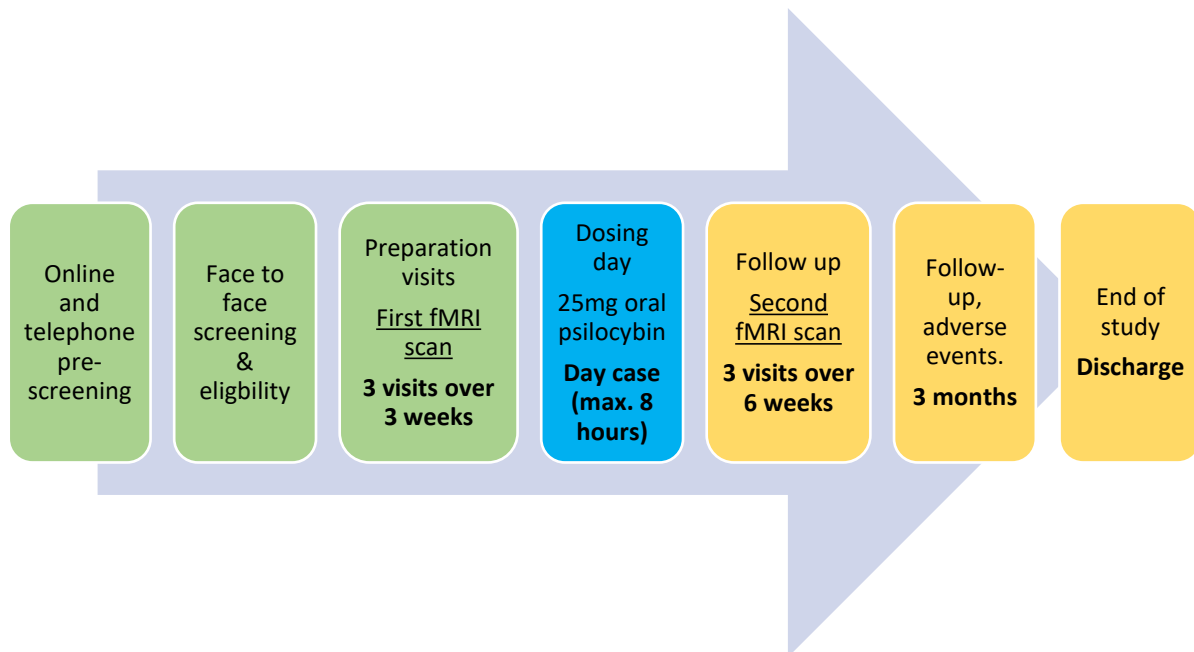
SCHEDULE OF EVENTS















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This Schedule of Events is designed to accompany the 'Main Document' PIS which will also have been given to you. The purpose of this document is to explain in more detail what will happen at each visit during the study. This is for informational purposes only.

Study Design

This study will have three phases: screening and preparation, dosing, and follow-up. Some of the visits will be longer than others. At each visit you will see a study doctor, and at most visits you will see a study therapist. At each visit you will have at least a short health and medication check by a study doctor. We will take written informed consent at the screening visit.



	Screening & preparation				Dosing	Follow-up				
Visit length (hrs)	4	2	2	6	8	2	6	2	2	2
Screening										
Medic										
Therapist		Prep.	Prep.	Prep.	Dose	Integ.	Integ.	Integ.	Integ.	
Dosing										
fMRI										

During the screening visit you will be asked questions about yourself and about your illness. We will also undertake basic physical tests such as blood tests, an ECG, your weight, and vital signs (e.g., your blood pressure). We will also do a basic urine test for physical illness, as well as a urine drug screen and a pregnancy test (the latter only if relevant). We will repeat some of the tests, such as the pregnancy test (if applicable), at the Baseline visit.

During the preparation sessions the study team will check in on you and you will speak to your therapist about the upcoming dosing. In some of the sessions after the Screening Visit you will be asked brief questions by the study doctor about your mood. On some occasions you will also be asked if you have had any suicidal thoughts. The clinicians involved in this study have lots of experience asking and responding to these sorts of questions. During these sessions you will also be asked to fill out several short questionnaires (either written or on a laptop computer) which will vary between visits. The questionnaires we will use are listed further down the document.

The sessions which incorporate the fMRI scanning will last longer. This is because the scanning itself will take around 60-90 mins, and the fact that we may not be able to guarantee an MRI slot at a particular time given that they are often in high demand.

The follow-up sessions will be similar to the preparation sessions in that you will see your therapist and be asked to complete several questionnaires. The study team will always explicitly guide you on which scales you need to complete; you will not need to remember which ones to do, and you will never need to do any preparation for these scales.

Study Assessments

In this study we are using a lot of different assessments in the study. In the table below, we have indicated which assessments will be undertaken on each visit and how long they will take. The number in each box indicates the estimated time each assessment will take in minutes. The questionnaires are explained in more detail below. There will be other questionnaires which the study team will do with you at different visits (i.e., you will not need to fill in anything yourself); these will be explained to you at the relevant times during each visit.

Visit	1	2	3	4	5	6	7	8	9	10
Visit length (hrs)	4	2	2	6	8	2	6	2	2	2
Screening and investigations										
Screening and consent	180									
Medication review	15	5	5	5	5	5	5	5	5	5
Urine and blood tests	60									
Tasks										
Heartbeat tracking task				60			60			
fMRI scan (Libet's Clock Test)				90			90			
Structured qualitative interview								(90)		
Questionnaires										
Questionnaire: M3VAS	1									
Questionnaire: GAD-7	5									
Questionnaire: SETS	5			5						
Questionnaire: SAPAS	1									
Questionnaire: 5D-ASC						15				
Questionnaire: EDI						2				
Questionnaire: MDI	10			10			10			
Questionnaire: SDQ	10			10			10			
Questionnaire: BIPQ	5			5			5			
Questionnaire: SCS	10						10			
Questionnaire: SAPAS	1									

Questionnaire: ACE	5									
Questionnaire: TEC	10									
Questionnaire: MAIA-2				5			5			
Questionnaire: PPS				10						
Questionnaire: SSS				5						
Questionnaire: EBI							2			
Questionnaire: PsylS							5			
Questionnaire: IPPS				2						
Questionnaire: CEQ							5			
Questionnaire: WCS	2							2		

fMRI scan

You will have MRI scans on two separate visits. For some of the scan, you will be asked to lie back quietly with your eyes shut. Following this, you will undertake a task called Libet’s clock test. In this task, you remain lying in the scanner and watch a ball revolving around a clock face projected onto a computer screen which you will be able to see without moving. We will ask you press a button at a random time interval, and you will then be asked to note when you felt the urge to press the button. In total, each scanning session will take around 90 minutes.

Heartbeat tracking task

In this task, which will be conducted on two visits, we will connect you via a probe on your finger to a computer which will measure your heartrate. This is not a painful or dangerous procedure. We will then ask you to try and measure your heartbeat and indicate whether it matched up to a series of tones which the computer will play. You will get instructions from a computer screen about how to do this. We will then ask you to indicate how confident you are about your decision on whether the heartbeat matches with the tones. You will have a practice trial prior to undertaking the task. In total, the duration of the task will be approximately 5-10 minutes (including instructions, questions, and practice trial).

Structured qualitative interview

We will offer you the opportunity of taking part in an optional interview during the third visit following the dosing session. The interview will last 1-2 hours. 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 doing. The interview will be recorded on an audio transcript which will be kept anonymously and securely on the King's College London cloud server. 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 quotes to be shared. If you would prefer not to consent to this, it will not affect your enrolment into the study or to the interview.

Stanford Expectations of Treatment Scale (SETS)

This scale measures your feelings and expectations about being in the trial, and how you think the dosing might affect you. You will do this twice, on a computer, and it takes approximately 1 minute to complete.

5-Dimensional Altered States of Consciousness Rating Scale (5D-ASC)

This questionnaire asks you to move a slider on a line to rate the effects of the dose. It focusses on some of the experiences people have reported when using psychedelics and asks you how strongly you felt certain things during the dosing experience. You will do this once, on a computer, and it takes approximately 15 minutes to complete.

Ego Dissolution Inventory (EDI)

The EDI is a short scale aimed to assess the extent to which you feel you temporarily lost your sense of self ('ego dissolution') during a the dosing experience. You will do this scale once, and it takes approximately 2 minutes to complete.

Multiscale Dissociation Inventory (MDI)

This is a questionnaire on dissociative experiences. Some patients with FND may report subjective episodes of dissociation, which you will be asked about. You may not be someone who experiences dissociation. You will do this scale three times, on a computer, and it takes approximately 10 minutes to complete.

The 20-item Somatoform Dissociation Questionnaire (SDQ)

This 20-item questionnaire is another way we can look at how much you have a tendency to dissociate. You may not be someone who experiences dissociation. You will complete this questionnaire three times, and it takes approximately 10 minutes to complete.

Brief Illness Perceptions Questionnaire (BIPQ)

This is a 9-item questionnaire designed to rapidly assess how you think and feel about your FND illness. You rate how much you agree with each item on a 0-10 response scale. You will do this questionnaire twice, on a computer, and it takes approximately 5 minutes to complete.

Self Compassion Scale (SCS)

The Self Compassion Scale is 26-item questionnaire. Self-compassion means being kind and understanding toward oneself. You will complete this questionnaire twice, on a computer, and it takes approximately 10 minutes to complete.

Maudsley 3-Item Visual Analogue Scale (M3VAS)

The M3VAS is a 3-item questionnaire which asks you to indicate quality of your mood, your experience of pleasure, and your experience of suicidal thoughts or feelings. You will do this questionnaire four times, and it takes approximately 1 minute to complete.

Generalised Anxiety Disorder Scale (GAD-7)

The GAD-7 is a 7-item questionnaire covering the most commonly occurring anxiety symptoms. You will do this questionnaire four times, on a computer, and it takes approximately 5 minutes to complete.

Short Assessment of Personality Scale (SAPAS)

The SAPAS is a very short assessment of your personality. You will do this questionnaire once, on a computer, and it takes approximately 1 minute to complete.

The Revised Fibromyalgia Impact Questionnaire (FIQR)

The FIQR is an instrument used in the evaluation of fibromyalgia patients. It assesses three aspects: what you are able to do, overall impact of your illness, and the symptoms you are experiencing. There is significant overlap between the things the FIQR looks at and the very common 'associated' symptoms of FND, such as pain and fatigue. You will do this questionnaire twice, at screening and at the end of the study. It will take around 10 minutes to complete.

Adverse Childhood Experiences (ACE)

The ACE is a 10-item questionnaire asks you about childhood life events and the extent to which the events were traumatic. You may not be someone who has had any experience of adverse or traumatic events. You will complete this questionnaire once, as part of screening, and it takes less than 5 minutes to complete.

Traumatic Experiences Checklist (TEC)

The TEC is questionnaire which asks you about traumatic events, with a focus on those which may have affected you in adulthood and those which are associated with post-traumatic stress disorder (PTSD). You will do this questionnaire once, as part of screening, and it takes around 10 minutes to complete.

Multidimensional Assessment of Interoceptive Awareness: Version 2 (MAIA-2)

The MAIA-2 is a 37-item questionnaire about 'interoception', which means awareness of bodily sensations, such as breathing and heart rate. You will do this questionnaire twice, and it takes around 10 minutes to complete.

Psychedelic Preparedness Scale (PPS)

The PPS is a 20-item questionnaire which asks you about how ready you feel for the psychedelic experience. You will do this questionnaire once, the day before dosing, and it takes around 5-10 minutes to complete.

Short Suggestibility Scale (SSS)

The Short Suggestibility Scale (SSS) is a 21-item questionnaire which asks about factors related to suggestibility. Suggestibility is a personality trait that reflects a general tendency to internalise and accept messages. You will do this questionnaire once, the day before dosing, and it takes around 5 minutes to complete.

Emotional Breakthrough Inventory (EBI)

The Emotional Breakthrough inventory is a short six item questionnaire which assesses emotional breakthroughs during the psychedelic experience. You will do this questionnaire once, the day after dosing, and it takes around 2 minutes to complete.

Psychological Insight Scale (PsyIS)

The Psychological Insight Scale is a six- to seven-item questionnaire that enquires about psychological insights after a psychedelic experience and accompanied behavioural changes. You will do this questionnaire once, the day after dosing, and it takes around 2 minutes to complete.

Imperial Psychedelic Predictor Scale (IPPS)

The Imperial Psychedelic Predictor Scale is a short 9-item scale measuring factors which helps assess knowledge of psychedelic preparedness in controlled settings. You will do this questionnaire once, the day before dosing, and it takes around 2 minutes to complete.

Challenging Experiences Scale (CEQ)

The Challenging Experience Questionnaire is a 26-item questionnaire which assesses difficult aspects of a psychedelic experience, such as feelings of unpleasant emotions. You will do this questionnaire once, the day after dosing, and it takes around 5 minutes to complete.

Watts Connectedness Scale (WCS)

The Watts Connectedness Scale (WCS) is a 19-item questionnaire which measures degree of felt connection to 'self', 'others' and the 'world. You will do this questionnaire twice, at screening and a week after dosing, and it takes around 5 minutes to complete.