King's College London

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PG Cert/PG Dip/MSc Examination

******** Research Skills: From Reviewing and Critical Analysis to Research Ethics
Coursework 2 Paper

Final word count: 1641
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Student ID Number ********* Date 24/02/2022

INFORMATION SHEET FOR PARTICIPANTS

TITLE (2.5%)
Psilocybin and Supportive Therapy for Major Depressive Disorder

Invitation Paragraph (7.5%)

We would like to invite you to participate in a research study designed by The Johns Hopkins Center for Psychedelic & Consciousness Research. The goal of this study is to better understand the effects of psilocybin therapy on individuals with major depressive disorder (MDD).

Please read through this information sheet carefully. If there is anything that is unclear, please reach out to us with your questions and/or concerns.

You're more than welcome to discuss details of the study with others if you wish. Your participation is voluntary and can be withdrawn at any time upon your request.

What is the purpose of the study? (20%)

The purpose of this study is to better understand the effect of psilocybin in a therapeutic setting, on individuals with major depressive disorder.

Psilocybin is a substance traditionally found in nature. Psilocybin can greatly alter human perception depending on the amount taken. This altered perception and resulting change in world view can result in both positive and negative outcomes. There is no way of knowing exactly what a person will experience in their session. For this reason, the therapeutic approach applied in this study is a necessary component. It is important that people undergoing a psilocybin induced experience have the necessary support to make sure they are in a safe environment physically and that they have access to psychological support if needed.

Depression is typically described by many as low mood accompanied with feelings of sadness or hopelessness. Major Depressive Disorder (MDD) is a specific type of depression that is persistent (for at least two weeks) and compromises a person's ability to function in life. Symptoms can include a lack of energy, inability to experience pleasure, low mood, chronic fatigue, difficulty sleeping, and a lack of appetite. Medical professionals can make a diagnosis based on their evaluation. Additionally, people can take assessments designed to measure symptoms that would indicate the presence of MDD. Treatment for MDD can vary but generally includes therapeutic approach(es) and/or antidepressants.

There is still uncertainty as to whether psilocybin in the context of supportive therapy is an effective treatment for people diagnosed with MDD. The purpose of our research is to better understand the effects of psilocybin and supportive therapy on people diagnosed with MDD.

Why have I been invited to take part? (5%)

We have been notified by an organization you are associated with that you may be willing to participate. After careful evaluation we have determined that you are a good fit for the next step in the screening process. If you are accepted into the study your participation is entirely voluntary, and you may leave the study at any point.

What happens to me if I take part? (25%)

By taking part in this study, you will participate in an 8-week process that includes preparation, psilocybin therapy sessions, and follow-up sessions. Prior to enrolment, we must conduct a final screening assessment in the absence of anti-depressants. For the purposes of this study, anti-depressant use must be discontinued for at least 5 half-lives prior to screening and up to 4 months after enrolment. The half-life of a drug is defined as the time it takes to reach a 50% concentration in the body after consumption. For example, if a drug has a half-life of 1 day, we will need that person to abstain from using that drug for 5 days. Again, that is an example and is not based on you and your circumstances. Please

consult with your prescribing medical professional prior to discontinuation of anti-depressants.

After this in-person screening assessment all participants moving forward with the study will take a baseline assessment and will be randomly placed in an immediate treatment group or a waitlist treatment group. Participants in the waitlist treatment group will go through the same intervention, the only difference is that the waitlist group will start 4-weeks after the immediate intervention group.

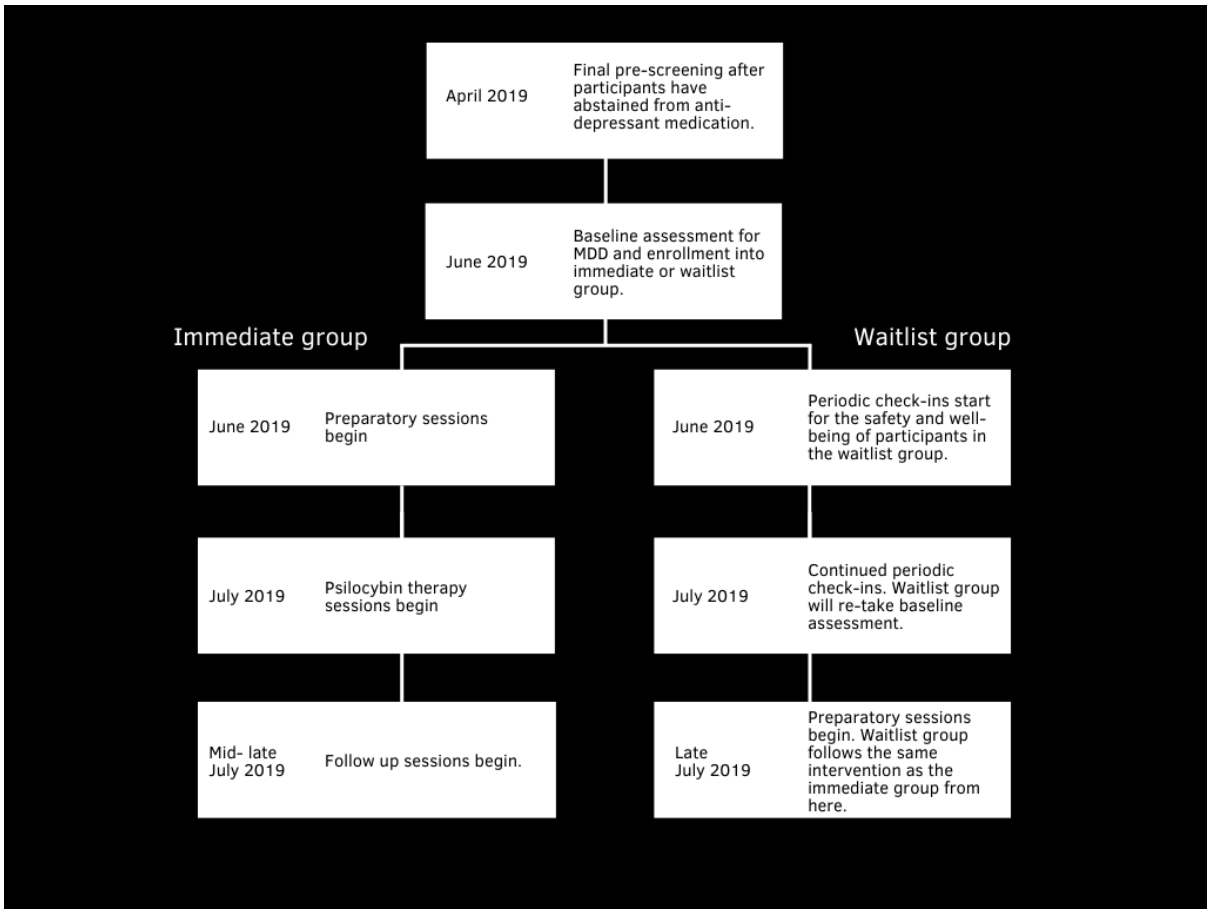
The intervention in this study consists of 18 in-person visits, 2 of which are day-long (about 11 hours) psilocybin sessions. All in-person visits for preparatory, psilocybin, and integration sessions will have two facilitators/guides present for the duration of the session. The only exception is in the case of small breaks for one facilitator at a time during longer sessions. Preparation sessions will take about 8 hours across two visits prior to psilocybin therapy sessions. One goal of the preparation sessions is to get to know you and your past experiences. The other goal of preparation sessions is to inform you on the nature of the psilocybin experience and possible effects.

Psilocybin sessions will be conducted after preparation sessions are completed. You will arrive the morning of to get comfortable in our therapy room. Except for small breaks, two facilitators will be there to assist you throughout your experience as needed. Research staff will be monitoring your heart rate and blood pressure throughout the session. The onset of effects varies but generally occurs between 30-120min. Psilocybin has an active effect for about 4-6 hours depending on the person and dosage. You must have someone pick you up after each psilocybin session. We also ask that you complete a session report in addition to the provided post-session questionnaires. The session report is essentially a narrative of your experience written however you see fit. The day after each psilocybin session you will come in to discuss your experience. The second session follows the same process and will occur about a week and a half after the first session.

After both psilocybin therapy sessions are completed, participants will visit the facility for follow up sessions. Follow up sessions are intended to help you make sense of your unique experiences.

You will have the option of participating in two MRI scans as a part of this study. More information regarding MRI scans will be provided in a separate information sheet, should you choose to participate.

The chart below outlines the general process. This chart does not include every activity but is meant to provide an overview of the study.



Am I eligible to participate in this study? (20%)

The final screening assessment is designed to help us determine whether you are eligible to participate in the study. We will determine the presence and severity of MDD using the Structured Clinical Interview and the GRID-Hamilton Depression Rating Scale. Each

assessment is designed to measure depression in adults, and both are widely accepted in the research community. After the in-person screening, participants will take a baseline assessment prior to officially enrolling in the study. Finally, participants will be randomly placed in the immediate intervention or the waitlist group. Below is a bullet-point breakdown of eligibility criteria.

You are eligible to participate if you…

- Are experiencing a moderate to severe episode of Major Depressive Disorder (MDD) at the time of the in-person screening and at baseline assessment.
- Are between the ages of 21 and 75.
- Have abstained from anti-depressant use for at least 5 half-lives prior to in-person screening assessment.
- (Women participants) Agree to use contraception to prevent pregnancy during the study.

You are NOT eligible to participate if you…

- Have an uncontrolled cardiovascular condition or are otherwise medically unstable.
- Have had a personal or family history of psychotic or bipolar episodes.
- Moderate to severe alcohol and/or drug-use disorder within the past year.
- Have used ketamine and/or classic psychedelics (LSD, psilocybin, DMT, mescaline, etc.) more than 10 times in your lifetime.
- Have used ketamine and/or classic psychedelics within the past 6 months.
- (Women participants) Are pregnant or nursing.

What are the possible benefits and risks of taking part? (20%)

There are potential benefits and risks associated with this study.

Physical risk associated with the study is relatively low. The tendency to become addicted to psilocybin is very low and the risk of overdose is low. It takes a large amount of psilocybin to cause physical harm to the average person while only a small amount is needed to induce a

response. The risk of psychological harm is less certain. Each person's experience is wholly unique and unpredictable. For example, in a relatively brief timeframe a person's experience can range from joy and positive imagery to no visual stimulus and a feeling of fear. Previous studies conducted at Johns Hopkins have indicated the importance of set and setting before-hand and a willingness to embrace whatever one is experiencing in the moment. Though we encourage participants to embrace challenging situations, there are psychological safety protocols in place and options for quickly reducing the effect of psilocybin in the case of an overwhelming experience.

Previous research has demonstrated potential benefits associated with undergoing a psilocybin experience in the context of supportive therapy. As a research community we are not certain that any benefit will come about from psychedelics. This is precisely why we are conducting this study. Psilocybin has not been researched in people diagnosed with MDD. Psilocybin has been studied in people diagnosed with substance use disorder, treatment-resistant depression, and anxiety associated with a terminal cancer diagnosis. Each study found that a psychedelic used in combination with supportive therapy tended to produce significant & positive change in participants as a group. Again, there is no guarantee that any one person will experience a benefit by participating. The hope is that through this study we can gain greater insight into the nature of psilocybin.

By participating in this study, you are contributing to a rapidly developing body of knowledge about psilocybin. News outlets today tend to inflate positive findings while news reports in the 20th century inflated fear around potential risks. The fundamental benefit is in collectively discovering a greater truth of the risks and benefits associated psilocybin in the context of supportive therapy.

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*[**PLEASE NOTE:** Participant information sheets normally also provide information on data protection/confidentiality, dissemination of results, funding, and contact information. You*

*are **not** required to include these sections in your coursework. You are also **not** required to include the consent form].*

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