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Participant Information Sheet

Assessing the effects of LSD microdosing in healthy menstruating persons (MDMENS)

Formal Study title: An open-label trial to test menstrual cycle effects and tolerance to LSD microdosing in healthy menstruating persons (MDMENS).

Sponsor: The University of Auckland, Auckland 1023, New Zealand.

Lead Researcher: Professor Suresh Muthukumaraswamy

Study Site: Clinical Research Centre, Building 507, Grafton Campus.

Contact phone number: 64 09 9232787

Ethics committee ref.: 2024 FULL 19211

You are invited to take part in a study investigating potential interactions between lysergic acid diethylamide (LSD) microdosing and the menstrual cycle. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 19 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

It is up to you if you take part in this study or not. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you don't want to take part, you don't have to give a reason. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive from us or your participation in future studies.

If you take part in the study you have the right to access any information about you collected during the study after your completion or withdrawal from the study.

If we learn anything about your health status or the medications to be tested during the study that affects your health you will be informed of this.

WHAT IS THE PURPOSE OF THE STUDY?

In this study we are investigating the effects that very small doses of LSD have on brain and behaviour in persons who menstruate. Taking small doses of LSD is called microdosing. Unlike large doses of LSD, microdosing does not make you "trip". Scientists don't know yet whether the peoples' reactions to LSD microdoses are affected by the phase of the menstrual cycle. The first purpose of this study is to investigate the possibility that the menstrual cycle affects the response to LSD microdoses.

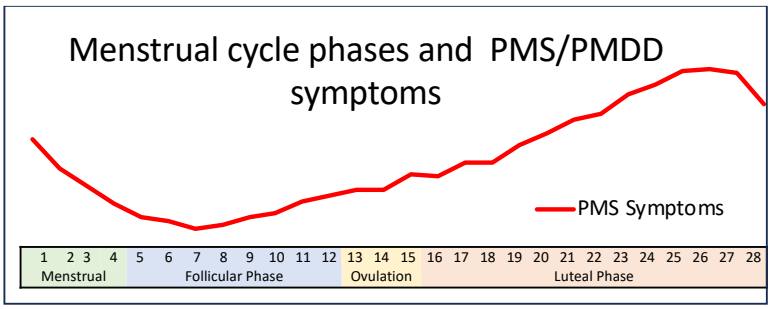
There are anecdotal claims that taking microdosing LSD can help relieve mood disturbances in premenstrual syndrome (PMS) and its most extreme form, called premenstrual dysphoric disorder (PMDD). The claims that LSD microdosing can help with PMS/PMDD has not yet been tested in clinical trials. The second aim of this study is to test whether participants develop tolerance to microdoses of LSD which will help devise a treatment regimen for a clinical trial in PMDD patients.

HOW IS THE STUDY DESIGNED?

This study aims to recruit 21 persons who menstruate who experience at most mild premenstrual symptoms. This study is an open-label trial which means that all individuals who take part in the trial will receive LSD microdoses. There is no placebo in this trial.

This study is designed around the menstrual cycle. It is useful to understand the basics of the menstrual cycle and mood in order to understand how the study is designed. This is shown in the figure below. The first day of the menstrual cycle is at the start of menstruation (full flow not just spotting) and lasts a few days. After menstruation ends, the next phase is the follicular phase and is when PMS/PMDD symptoms are typically at their lowest. Around day 14 after menstruation, ovulation occurs and after ovulation the luteal phase begins. Near the end of the luteal phase PMS/PMDD symptoms reach their peak. Importantly, although the average menstrual cycle is 28 days this can vary between persons who menstruate and vary between an individual's own cycles. To time study visits/events correctly we need participants to track

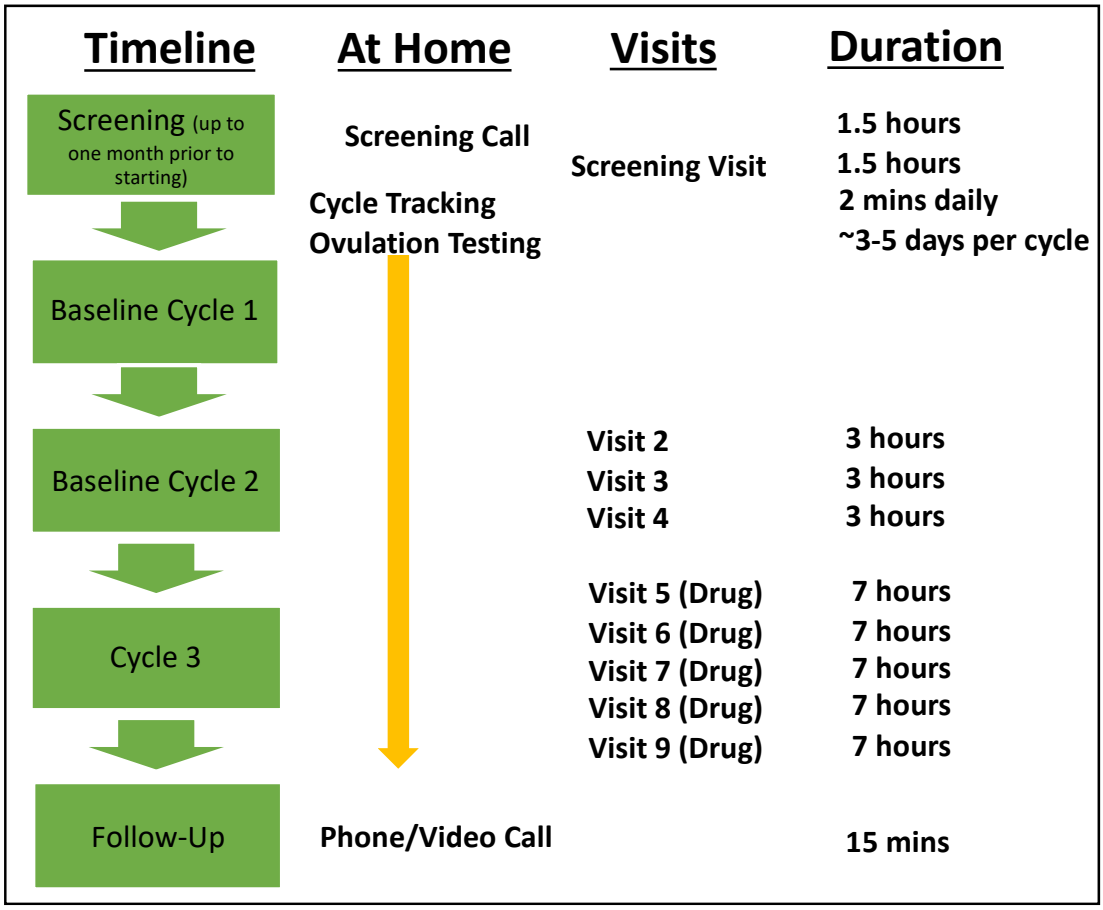
their menstrual cycles and report them to us (more on this below). We time follicular phase study events from the onset of menstruation. For luteal phase study events we time these relative to when ovulation occurs. To do this we need participants to perform and tell us the results of home ovulation testing.



To participate in this trial, you will have to undergo a psychological and physical evaluation to ensure you meet the inclusion and exclusion criteria (listed below under "Who can take part in the study?"). This will be done in two parts.

- The first part – a psychological evaluation - will be done by video call or in person. This will take approximately 1.5 hours. If you are still eligible, then you will be invited to attend our study site for a screening visit. At that assessment we will take a number of physical measurements, including blood samples, urine samples to check for recreational drug use, blood pressure measurements and an electrocardiogram (ECG) (recordings from your heart). This will take approximately 1.5 hours.
- If you are still eligible, we will organise a video call with you. At this point we will ask you to track your menstrual cycle and mood using a daily questionnaire called the "Daily Record of Severity of Problems" (DRSP) for the rest of the study. We will send you out home ovulation testing kits by post so we can precisely track your cycle timing. You would need to test for ovulation for 3-5 days of each cycle using urine testing but sometimes up to ten days of testing might be needed. At this point we will also organise your first study visits.
- The next two menstrual cycles will involve filling the DRSP every day and making three visits to our study site timed to your 2nd menstrual cycle. One will occur in the follicular phase (~5-9) days after you menstruate, one during ovulation (around two weeks after menstruation and one during your luteal phase (10-14 days after ovulation). We will work out the precise dates depending on your individual cycle timings. These dates may change with relatively short notice if your menstrual cycle behaves irregularly.
- After two cycles we will review your DRSP data and only then are we able to confirm whether you are still eligible to continue with the trial. It is possible that you may not meet our inclusion criteria and we would need to withdraw you from the trial. We apologise if this happens to you. You will receive a reimbursement if this happens (see "Will any costs be reimbursed?" below).
- The next menstrual cycle involves 5 visits to our laboratory. Three will occur in the follicular phase (~5-9) days after you menstruate, one during ovulation (two weeks after menstruation and one during your luteal phase (10-14 days after ovulation). In these sessions you will receive LSD microdoses and be observed for six hours and have blood samples taken..
- One month after that you will receive a follow-up phone call to check on your health.
- **You are welcome to bring a family/whānau member or other support person to any clinic visit.**
- The study design is a little complicated so we have included a picture for you below showing the study pattern and your time commitments.

- We will send you email reminders to remind you of visit timings .



WHO CAN TAKE PART IN THE STUDY?

You have asked to participate in this study and have indicated to us that you menstruate without experiencing more than mild PMS and are aged between 18-46.

You will not be eligible to participate in this study if you:

- Or an immediate family member have ever had schizophrenia, psychosis, bipolar disorder
- Currently have depression, any anxiety disorder, any eating disorder or PTSD
- Suffer from moderate to severe PMS
- Are feeling suicidal. See "What are the possible risks of this study?" below for more information
- Take certain prescription medicines
- Have certain medical conditions – particularly ones that affect your kidneys, liver and heart
- Have recently had a substance use disorder
- Are using/ have used hormonal contraception in the last three months
- Are pregnant, breastfeeding, or of child-bearing potential, heterosexually active and not willing to use an appropriate method of contraception. See section "What are the possible risks of this study?" for more information

During the study we ask that you please:

- Abstain from alcohol for the 24 hours before study visits.
- Abstain from recreational drugs for the duration of the study
- Do not consume caffeine on microdosing days

Please note: the study drug contains small amounts of alcohol (~ 1ml) that is given under your tongue. For some people will taste unpleasant or they may not wish to consume any alcohol. Let us know if this will be a problem for you.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Your participation starts with some screening sessions to determine your eligibility to take part in the study. A study team member will contact you by phone/email to set-up the screening process. You'll then be sent a consent form and questionnaires to complete from home before the screening video call.

SCREENING – up to 28 days before starting	
Screening (Video call*) 1.5 hours	We will ask you questions about your: • Demographics • Medical history • Psychiatric history. This includes you telling us your personal history and us asking you some standardised questions •
If you are still eligible then you will be asked to attend a screening visit in person	
Screening (Visit 1) 1.5 hours	We will collect: • Height and weight information • Questionnaires about your personality • Blood samples (30 ml of blood) to test: kidney, liver, thyroid function, for pregnancy and to measure your hormone/iron levels. 30 ml is about 6 teaspoons. • Blood pressure, heart rate and body temperature • Urine drug screen for recreational drugs and a breathalyser test • Electrocardiogram (ECG) recordings of your heart

*This can be done in person if you prefer or don't have access to video call technology

Provisional confirmation of enrolment: Once we have all your test results back, we will contact you to organise the rest of the study via a remote call. If we are still unsure about eligibility we may contact you to get further information from you.

Set-up – Start Day	
Set-up call (Video call) 30 minutes	This will involve: • Show you how to complete the symptom tracking questionnaire • Set-up a Garmin activity tracker application on your phone and mail the tracker (watch) out to you (details below) • Send out home ovulation test kits to you and provide you instructions on how to use • Answer any questions that you have

*If you don't have an appropriate smart phone or adequate data plan we will provide these for you.

Menstrual Cycle 1 (~ 28 days – starts at menstruation)	
No visits	At home you will need to: • Complete the symptom tracking each night • Perform ovulation testing and report results to us

Menstrual Cycle 2 (~ 28 days)	
Three visits each taking three hours	At home you will need to: • Complete the symptom tracking each night • Perform ovulation testing and report results to us Each visit will involve: • An EEG procedure which lasts 90 minutes (see below) • Questionnaires about your current mental health • Blood pressure, heart rate and body temperature measurement • Blood samples (20 ml of blood) (including pregnancy test) • Urine drug screen for recreational drugs and a breathalyser test The visits will occur around days 5-9 after menses, the day of or after ovulation and 10-14 days after ovulation depending on your cycle timing.

Confirmation of enrolment: After completing two months of menstrual cycle tracking we can now confirm whether you are still eligible to participate in the trial. It is possible that you may not meet our inclusion criteria and we would need to withdraw you from the trial. We apologise if this happens to you. You will receive a reimbursement if this happens (see "Will any costs be reimbursed?" below).

Menstrual Cycle 3 (~ 28 days)	
Five visits each taking seven hours	At home you will need to: • Complete the symptom tracking each night • Perform ovulation testing and report results to us Each visit will involve: • Questionnaires about your current mental health • Urine drug screen for recreational drugs and a breathalyser test • Receiving a 30 microgram dose of LSD after which you will be observed for 6 hours • An EEG procedure (see below) • Regular blood pressure, heart rate and body temperature measurement • Regular blood samples (80 ml of blood) (including pregnancy test) taken through an intravenous cannula • Answer regular questions about how you are feeling in terms of potential drug effects • Electrocardiogram (ECG) recordings of your heart (last visit)

	• Blood samples (30 ml of blood) to test: kidney, liver, thyroid function, for pregnancy testing and to measure your hormone levels. 30 ml is about 5 teaspoons (last visit) • Measuring your weight (last visit) • Interview (Last visit) Three visits will occur around days 5-9 after menses, one the day of or after ovulation. One visit will then occur on consecutive days 9-13 days after ovulation depending on your cycle timing.

One month after the study ends we will give you a quick follow-up call to check on your health.

ECG:
ECG involves putting a number of electrodes on your chest. This is quite close to your breast area. If this makes you uncomfortable let us know. We will do our best to find a study team member of your own gender to perform this procedure or be in the room if preferred - but this is subject to availability of staff.

EEG:
An EEG recording involves putting on a soft cap that has 64 electrodes (black plugs in the image below). The electrodes sit near your scalp and record electrical activity from your brain while you complete simple tasks on a computer. A good electrical signal is reached by using an electrolyte gel to ensure good contact with your skin. After the recording session, the electrolyte gel needs to be removed from the hair, which is easily done by a hair wash. We have facilities for you to wash your hair and will provide you with a towel and shampoo.

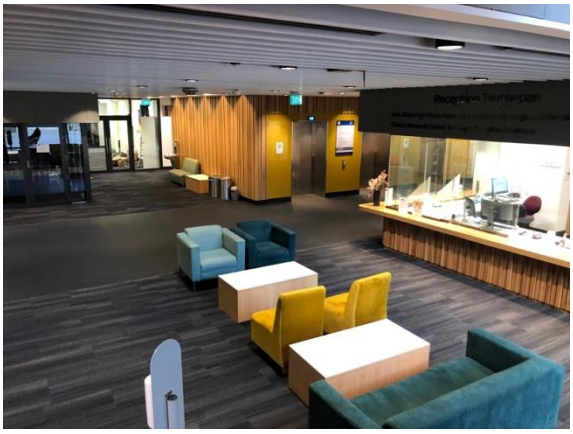
The EEG takes around 15-30 minutes to setup, and we will ask you to simple tasks while we record the EEG for up to two hours intermittently during the session. During visits 5-9 you will wear the EEG cap for six hours. We will loosen the strap on the EEG so you can be comfortable during the periods where we are not recording the EEG. To make the set-up easier please come to the study days with clean, dry hair with no hair-care products in your hair.

The EEG procedure consists of a set of easy visual and auditory tasks. One of the tasks is a “gambling task” with a small monetary reward ($20 on average). The EEG recordings we make are not able to detect clinical abnormalities and are made for scientific purposes only.

MEDIA AND SOCIAL MEDIA:
Please don’t post on social media or talk to media organisations about your involvement in the study until the study is complete (we will let you know when it is finished). This is to prevent your viewpoints influencing those of future trial participants.

WHAT IS YOUR RESEARCH CENTER LIKE?

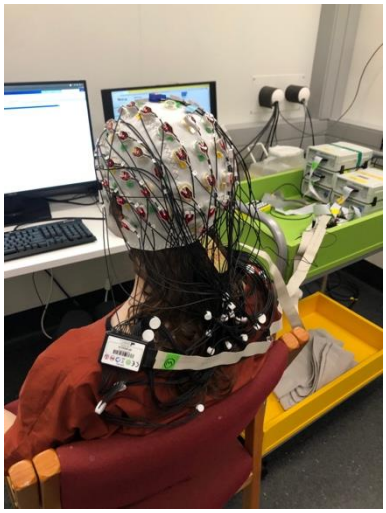
Here we provide some pictures of some of the main locations and procedures to help you make your choice about participating.



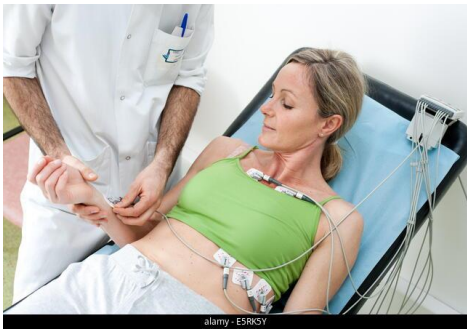
Our research centre reception

The main research room

The EEG room



An EEG being recorded



ECG

Oral syringe and vial for microdosing

WHAT WILL HAPPEN TO MY *BLOOD AND URINE* SAMPLES?

The urine samples that you provide us during some visits will be tested for the use of recreational substances and then disposed of immediately.

Blood samples will be collected at various points in the study by the study team. All samples will be de-identified (no name on them) and no samples will be sent overseas.

Some blood samples will be sent to LabPlus for immediate analysis to look at simple health markers (e.g. liver and kidney function) to ensure participants are safe to be involved in the

research. These samples will have your date of birth and sex on them to aid diagnosis. If you are heterosexually active it is very important that you are not pregnant or become pregnant during this study. As such, LabPlus will also conduct blood pregnancy tests. For further information about the study requirements surrounding pregnancy; see below (Possible risks of this study). Only LabPlus will have access to these samples. The samples will be disposed of in accordance with LabPlus policy after they have been analysed. We will inform you of any unexpected results from these tests that could be of importance for you to know and suggest an appropriate course of action.

All other blood samples will be kept at The University of Auckland for scientific analysis for up to five years. Should you withdraw from the study your samples will continue to be analysed for the purposes of the study. We will be looking at the blood samples to look at levels of LSD in your body as well as protein, hormonal and inflammatory markers that might get changed by the drug. Any analyses of the samples you provide us will be only for the purposes of microdosing and/or mood disorder research.

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with storing your tissue should be discussed with your family/ whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose. Options for disposal of the blood samples with karakia and returning samples can be discussed during the screening visit. If there are additional things that we can do to meet your needs, please feel free to discuss these with the study team.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

In the event that a condition which is assessed to be a clinical abnormality is detected through a blood test or other exam you will be informed. Your general practitioner or other health professional of your choice will be notified with your consent.

The drug that we will use in this study are given at low doses. All your doses will be given under supervision at our research centre. The LSD has been prepared by a pharmaceutical company under strict manufacturing conditions to ensure the drug is pure.

Some blood samples will be obtained through an intravenous (IV) cannula. An IV cannula is a small flexible tube put into a vein in your arm, the same as if you have been on a drip in a hospital. This can cause side-effects. The most common of these are bruising, mild pain and feeling faint when it is put in.

At the dose we will give you (30 micrograms) you can expect to feel some stimulation, a bit like you feel after drinking a lot of coffee. This feeling should pass before you leave our laboratory.

Previous LSD microdosing studies in healthy volunteers have reported mild/moderate intensity headaches, nausea, vivid dreams and jitteriness in some participants which occur in <10% of participants. In a previous study we conducted in healthy male volunteers 4/40

volunteers were withdrawn due to being anxious after microdosing. You might also experience these negative effects. If you do, it is important to let us know so we can advise you.

You should be aware that LSD is a Class A controlled substance. Although given at low doses, taking this regularly may be incompatible with your employment conditions. You should discuss this with your employer and/or the study team before starting the study.

As a part of this research, we will ask you to complete a number of psychological questionnaires. These include questionnaires that ask about suicide. If these cause you distress our research team is available to support you or refer you to someone else who can.

We have a number of safety protocols in place to check and monitor your well-being during the study. We monitor the questionnaires you complete at home. If you raise any health issues we will follow these up the next day with you. If you have any questions about this, please feel free to speak with your doctor or with study staff. We are happy to answer any questions you might have.

It has been theorised that taking LSD might affect your heart health – in particular causing hardening of your heart valves. This is quite unlikely as there have been no cases of this reported despite 70 years of recreational LSD use. This is why we are recording ECG in this study.

Reproductive risks for heterosexually active participants of child-bearing potential

The effects of LSD in pregnancy and breastfeeding are not known, but there is a low risk it may cause birth defects or foetal deaths, and/or be passed on in breast milk. If you are pregnant or breastfeeding, you cannot take part in this study.

It is thought that the risk of LSD for unborn children is very low, but this has not been proven. As such, if you are heterosexually active and of child-bearing potential (able to become pregnant), it is very important that you do not become pregnant during this study. You must use one of the methods of contraception listed below during the treatment cycles (Cycles 3 and 4). Methods of contraception include:

- Intra-uterine device (IUD) containing copper
- Female sterilisation (e.g. bilateral tubal ligation ('clipping or tying tubes')
- Be in an exclusive relationship with a sterile male (vasectomy)
- Condoms (external / internal)

Please note: condoms/IUDs are not highly effective methods of contraception You must also agree not to donate eggs from when the third menstrual cycles starts in the study until at least 3 months after your last dose of study drug.

If you do become pregnant during the study, you must tell a member of the study team as soon as possible. If you are pregnant, this will result in the cessation of the study for you and we will ask to collect information about the pregnancy and outcomes, including that of the infant.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct benefits for you from taking part in the study apart from receiving reimbursement. The results from this study may help advance knowledge on the biology of PMS/PMDD and open new avenues of treatment to help people with PMS/PMDD in the future.

WILL ANY COSTS BE REIMBURSED?

We will pay for any costs that you incur by taking part in the study. If you require a taxi to get to and from the study, then we can arrange and pay for this. We recognise that taking part in the study will take up a lot of your time. You will be reimbursed the sum of $1,000 following the final study visit. You will be responsible for any tax obligations arising (income tax, ACC). An extra $20 can be gained each time based on results from one of the EEG tasks which is performed seven times.

To be able to receive payment for participating you must be eligible to work in NZ for the entire duration of the study. If you are no longer eligible to work in NZ during the study, you will be withdrawn from the study and your reimbursement will be a pro-rata of the total amount.

If you are withdrawn from the study for medical reasons, having received trial medication, you will receive reimbursement in full.

If you leave the study of your own choice or are released from the study for non-medical reasons, you will receive a partial reimbursement (a pro-rata reimbursement) according to how far you contributed to the study. The pro-rata reimbursement for completing the Baseline period of the study only is $500. If you complete the screening visit assessments and are found not eligible for the study, you will receive a $30 gift card.

WHAT IF SOMETHING GOES WRONG?

As this research study is for the principal benefit of its commercial sponsor The University of Auckland, if you are injured as a result of taking part in this study you **won't** be eligible for compensation from ACC.

However, the University of Auckland has satisfied the Southern Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.

New Zealand ethical standards require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand's ACC scheme.

Some sponsors voluntarily commit to providing compensation in accordance with guidelines that they have agreed between themselves, called the Medicines New Zealand Guidelines (Industry Guidelines). These are often referred to for information on compensation for commercial clinical trials. There are some important points to know about the Industry Guidelines:

- On their own they are not legally enforceable and may not provide ACC equivalent compensation.

- There are limitations on when compensation is available, for example compensation may be available for more serious, enduring injuries, and not for temporary pain or discomfort or less serious or curable complaints.
- Unlike ACC, the guidelines do not provide compensation on a no-fault basis:
- The Sponsor may not accept the compensation claim if:
  - Your injury was caused by the investigators, or;
  - There was a deviation from the proposed research plan, or;
  - Your injury was caused solely by you.

An initial decision whether to compensate you would be made the by the sponsor and/or its insurers.

If they decide not to compensate you, you may be able to take action through the Courts for compensation, but it could be expensive and lengthy, and you might require legal representation. You would need to be able to show that your injury was caused by participation in the trial.

You are strongly advised to read the Industry Guidelines and ask questions if you are unsure about what they mean for you.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study, the study doctors/researchers, nurses and other study staff will record information about you and your study participation. This includes the results of any study assessments. If needed, information from your hospital records and your GP may also be collected; access to your records is limited to that required for study purposes. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address, audio recordings). The following groups may have access to your identifiable information:

- University of Auckland investigators, staff and PhD students (to complete study assessments).
- Study monitors, to make sure the study is being run properly and that the data collected is accurate.
- Your GP may be notified of your participation in this study with your consent.
- University of Auckland representatives, if you make a compensation claim for study-related injury. Identifiable information is required in order to assess your claim.
- University of Auckland representatives, ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Your usual doctor (your GP or specialist), if a study test gives an unexpected result that could be important for your health or well-being. This allows appropriate follow-up to be arranged.
- LabPlus (your blood samples have your Date of Birth on them).
- Transcription services for recorded audio data only.

- Rarely, it may be necessary for a study doctor to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person or if the information is required in certain legal situations.
- As part of the research we will record audio from some of your psychiatric assessments, for quality checking purposes), audio journals if you choose to keep audio journals and speech recordings during study visits. These audio recordings will be used for scientific analysis. Access to these audio recordings is limited to the groups mentioned above and may be stored for up to fifteen years.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the study team. The study team will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information which may be sent and stored overseas:

- People and companies working with or for the University of Auckland, for the purposes of this study (this may include approximately 20 people and companies).
- Regulatory or other governmental agencies worldwide.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Anonymised Information.

The University of Auckland may remove the code from your de-identified information – this is called ‘anonymisation’. This makes it very difficult (but not impossible) to identify the information that belongs to you. The University of Auckland may share this anonymised information with other researchers and companies.

Future Research Using Your Information.

Your de-identified information will only be used for future research related to microdosing or mood disorders. This is mandatory.

This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

You will not get reports or other information about any / some research that is done using your information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

Security and Storage of Your Information.

Your identifiable information is held at The University of Auckland during the study. After the study it is stored for at least fifteen years. Your coded information will be entered into electronic

case report forms. Coded study information will be kept by the University of Auckland in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Your coded information may be sent overseas. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

This research includes basic information such as your ethnic group, geographic region, age range, and gender. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatise, or discriminate against members of the same groups as you.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

If you have any questions about the collection and use of information about you, you should ask the study team.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing a study team member.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

Ownership Rights.

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to The University of Auckland and MindBio Therapeutics Ltd. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

Use of New Technologies (Activity Tracking)

In this study use of a mobile Garmin activity tracker are mandatory components for study participation. We will provide you with the Activity tracker and if you do not have a mobile phone or data plan we will provide you with one or both as needed at no cost to you.

We will ask you to wear a Garmin Activity tracker for the duration of the study as we are interested in recording your activity and sleep during the study. These data will be sent to the Garmin website and to an associated company called Fitrockr.

In order to protect your privacy we will make dummy email addresses and accounts to associate with the watch that you will wear so that your personal information does not need to be registered with Garmin/Fitrockr. Before we give you the watch we will turn the GPS function off so that neither the research team nor anyone else can track your location. We would ask you not to turn the GPS functions on. Only the research team and you have access to your dummy account and password.

Although your activity tracker data is "de-identified" you should note that your data will be sorted overseas in both the United States for Garmin and in Germany for FitRockr. These companies may use your de-identified data for their own purposes beyond the aims of our study. Although these companies require consent to share your de-identified data with third parties we are unable to guarantee this is the case.

There are no costs to you involved with using the watch and its services. We will need to install the Garmin app on your phone so that your data can be transmitted from the watch to your phone to the Garmin/Fitrockr overseas data clouds. We will access your data from there. We will ask you to return the Activity tracker to us at the end of the study.

The full data policies of these companies are at these links:

https://www.fitrockr.com/health-solutions/privacy-policy/

https://www.garmin.com/en-NZ/privacy/connect/policy/#categoriesOfPersonalDataProcessedByGarmin

Māori Data Sovereignty

Māori data *sovereignty* is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have consulted with Māori research advisors about the collection, ownership, and use of study data.
- We will allow Māori organisations to access de-identified study data, for uses that may benefit Māori.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

You may withdraw your consent for the collection and use of your information at any time, by informing a member of the study team. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

CAN I FIND OUT THE RESULTS OF THE STUDY?

It can take quite a long time to analyse data from these kinds of studies. We hope to be able to tell you the final results one to two years after completion of the study. We plan to publish the results in specialised academic journals. If you want us to, we can send you a summary of the results in an easier format to read.

This trial is registered on the Australian New Zealand Clinical Trials Registry (ANZCTR). This can be accessed at anzctr.org.au

WHO IS FUNDING THE STUDY?

Funding for this trial has been provided by the Auckland Medical Research Foundation. Funding for the study drug has been provided by a company called MindBio Therapeutics Ltd. The study investigators are all affiliated with The University of Auckland and/or work for private healthcare providers in New Zealand. The University of Auckland has a licensing agreement in place with MindBio Therapeutics Ltd. and both parties may benefit commercially from the study being conducted. The data in this study will be included in several student PhD theses.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Southern Health and Disability Ethics Committee has approved this study.

The scientific aspects of this study have been approved by the Standing Committee on Therapeutic Trials (SCOTT), which is part of Medsafe. Medsafe have also approved the pharmaceutical quality of the study drug.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Suresh Muthukumaraswamy, Professor
Phone: +64 9 9232787
Email: sd.muthu@auckland.ac.nz

For urgent questions and concerns that arise during the study you can contact the study team on: **027 204 6170 or pmdd@auckland.ac.nz**

If you are experiencing suicidal thoughts you can contact:

The Auckland Mental Health Crisis team
Phone: 0800 800 717 (operating 24/7)

If you are in immediate danger, please contact 111 and ask for Police.

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@advocacy.org.nz
Website:	https://www.advocacy.org.nz/

For Māori cultural support please contact:
He Kamaka Waiora (Māori Health Team)
Phone: +64 9 486 8324 x 2324
Email: hkw@adhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Email:	hdecs@health.govt.nz
Phone:	0800 400 569 (Ministry of Health general enquiries)

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Private Bag 92019
Auckland
New Zealand

Building 505, Level 3, 85 Park Road, Grafton
Auckland 1142, New Zealand

Telephone: 64 9232787
Email: sd.muthu@auckland.ac.nz

Consent Form

Assessing the effects of LSD microdosing in healthy menstruating persons (MDMENS)]

Please tick to indicate you consent to the following

I have read the Participant Information Sheet, or have had it read to me in a language I understand, and I fully comprehend what it says.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
I consent to the research staff collecting and processing my information, including information about my health.
I consent to my information being sent overseas.
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.
I understand that there may be risks associated with the treatment in the event of me becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy.
I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste.
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I understand the compensation provisions in case of injury during the study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: