

Participant Information Sheet

Focus group and experimental study

People who drive under the influence of drugs

Project Title: *Characteristics of driver impairments under the chronic influence of illicit drugs and prescription medications. A simulated driving experiment.*

UQ Ethics Approval Number: 2020000434

You are invited to take part in a study exploring the prevalence, demographics, and attitudes of people who drive under the influence of drugs (DUID). This Participant Information Sheet describes what is involved in the study, and you should read it in full before deciding whether or not to participate. Please keep this information sheet as a record.

What is the purpose of this research?

Driving under the influence of drugs can have a large impact on the ability of people to drive safely on the road, creating a community concern due to the high social costs of severe or fatal crashes. This study aims to provide a better understanding of how illicit drugs affect people's ability to drive safely, as well as explore the beliefs and attitudes of these drivers towards DUID.

Am I eligible?

To participate in the experimental study you must meet the following criteria:

- Between the ages of 18 and 65 years
- Sleep more than 7 hours regularly
- Generally healthy with no clinically diagnosed sleep disorder or mental health issues
- Hold a valid driver's license (provisional or open)
- Drive a vehicle regularly (3+ days per week)
- Regularly use illicit drugs (i.e have used Cannabis, MDMA/Ecstasy, Methamphetamine or Ice on at least six occasions in the last six months)
- Do not use any prescription medication that causes drowsiness while driving including Antihistamines (Benadryl, Phenergan, Unisom), Muscle relaxants (Cyclobenzaprine, Dantrolene, Baclofen), Antidepressants (Amitriptyline, Lexapro, Celapram), Topiramate (Topamax), Beta-blockers (Lopressor, Carvedilol, Bisoprolol), Opioids (Tramadol, Oxycodone, Codeine), and Benzodiazepines (Temazepam, Valium, Xanax)
- Live within a 20 km radius of the Institute for Social Science Research (Indooroopilly, QLD).

Participation in the focus group eligibility criteria:

- Between the ages of 18 and 65 years
- Sleep more than 7 hours regularly
- Generally healthy with no clinically diagnosed sleep disorders or mental health issues
- Hold a valid driver's license (provisional or open)
- Drive a vehicle regularly (3+ days per week)
- Regularly use illicit drugs (i.e have used Cannabis, MDMA/Ecstasy, Methamphetamine or Ice on at least six occasions in the last six months)
- Do not use any prescription medication that causes drowsiness while driving (see list above)

If you experience any unanticipated changes in life circumstances that may affect your ability to engage in the experimental study, we ask you to notify the research team as soon as possible to discuss your ability to continue the study.

What does the research involve?

This study consists of a focus group study and an experimental study. You could participate in one of these components or both. Overall, these two studies will only require a small portion of your time, depending on which group of participants you are a part of. If you are participating in the focus group interviews, only a single 1-hour session of your time will be required. The focus groups will be held via Zoom with yourself and 2 other people. A research assistant will ask you and other interviewees some questions about your beliefs and thoughts on the risks of DUID, either alone or combined with other drugs and alcohol. The research assistant might take notes of your comments and the Zoom session will be recorded (audio only) for further extraction of data. The research team will offer a \$60 voucher for participating in the focus group interview session. In addition to the focus group study, you could participate in the experimental study.

If you are taking part in the experimental study you will be required to attend a one-hour induction session before commencing your participation in the experimental study (as shown in the study timeline). At the induction session, you will be asked to complete some questionnaires about your general health and sleep quality. The induction session will be conducted via Zoom with your participation starting on the day of the induction session. Please note that you will not be given any illicit drugs during your participation. Instead, you will be asked to report your typical times of use of illicit drugs (e.g. weekly, fortnightly, etc.) to identify the pattern of your drug use. The experimental study will run for two weeks (depending on your pattern of use). While, for the majority of the study period, you will only be asked to complete a short daily sleep diary every morning (that will be emailed you daily), you will be required to attend two 1.5-hour visits (taking 3 hours of your time) at ISSR. For the health and safety of participants, we will provide transportation in the form of an uber to and from ISSR. Based on your self-reported pattern of illicit drug use, the first visit will be held on a day of use (when the dose of drugs is highest in your body system). The second visit will be on a day before using the illicit drug(s) (when the dose of drugs is lowest in your body system).

At each laboratory session, you will be asked to complete some brief questionnaires. A research assistant will record your brain and heart activities continuously during the test session. Brain activity will be recorded by the placement of two electroencephalography (EEG) gold cup electrodes on your head and two electrocardiography (ECG) electrodes to your chest. The EEG and ECG techniques are non-invasive devices and do not cause any electrical shocks. You will be asked to complete some computerised tasks on an iPad and to wear special goggle frames to record your eye-blink and pupil size. You will be asked to drive on a driving simulator for 30 minutes while wearing the goggles. The research team is offering a \$60 voucher upon completion of each visit to ISSR to reimburse you for your time.

Experimental study timeline overview

ACTIVITY	TIMING
Pre-study Induction session, fill out questionnaires	Arranged time
Life, as usual, filling out the sleep diary	Week 1
ISSR visit 1 after drug use, 1.5-hour	End of week 1
Life, as usual, filling out the sleep diary	Week 2
ISSR visit 2 before the next drug use, 1.5-hour	End of week 2

Source of funding

The UQ Early Career Researcher Grant 2020 has funded this project.

Consenting to participate in the project and withdrawing from the research

If you are eligible for this study, you will be asked to provide your written consent to participate during the induction visit. Participation in this study is voluntary and you are under no obligation to consent to participate. If you do participate, you may withdraw at any stage of the study. We will remove any identifiable links between your data and your name following your exit from the study, ensuring your data remains non-identifiable. If you tick the relevant box in the Consent Form, we will remove your data from the dataset after your withdrawal. Withdrawing in any way from the study will have no adverse effects on your relationship with the researchers in this project or the Drug Trends Program staff or the University of Queensland.

Expected benefits

This study will not benefit you in terms of quitting drugs but will have a wide impact on the general population. This study will raise people's awareness of the effects of drugs on their driving and in turn the potential to reduce dangerous driving and therefore accidents on the road. The findings from this study will provide a better understanding of driver impairments and the sustainability of driver impairments while driving under the influence of illicit drugs as well as people's attitudes and beliefs towards this risky behaviour. Findings from this research will have the ability to inform harm reduction strategies and therefore reduce the risk of harm to communities as well as inform future research on the subject.

Risks

There are some potential risks of inconvenience and discomfort associated with your participation in this study. These include:

- Risk of disclosure of your illicit drug use. In this study, we will not ask you for any information about your employer or family members. To manage the risk of revealing your illicit drug use or driving under the influence of drugs or alcohol, we will not disclose this information to any third party (e.g. authorities, employer, or family members).
- Risk of involvement in road crashes while commuting to ISSR under the influence of illicit drugs: You will be transported to ISSR using Uber, there will not be a risk of road crashes due to illicit drug use while commuting to ISSR.
- Risk of disclosure of your beliefs and thoughts towards driving under the influence of drugs. The audio files and notes taken from the focus group interview will not be disclosed to any third party and will be treated confidentially.
- Discomfort with the devices used to measure brain activity (EEG) and heart rate (ECG). There is a possibility that you could be uncomfortable with the research assistants connecting these to your skin. These devices also involve using adhesive tape to ensure they maintain contact with your skin. You could experience a reaction to this adhesive tape, however, you will have these devices connected for a short time (approximately for one hour) and the risk of skin irritation within this length of time is minimal.
- There is a very small risk that you will experience motion sickness during the simulated driving task during the Laboratory Sessions. You will be asked to let the research team know of your sickness. We will also ensure that you can take breaks as required, and we will provide you with a comfortable rest space with light refreshments.
- There is a minimal psychological risk that answering questions about your drug user history will elicit uncomfortable thoughts and feelings. If you happen to experience difficult thoughts and emotions about your participation, please consider contacting one of the following services to obtain support: Lifeline Counselling 13 11 14; BeyondBlue 1300 22 4636 (24/7 Support and web counselling from 3 p.m. – 12 a.m.).

Confidentiality

All information and data collected as part of this study will be treated confidentially unless required by law. During the study, you will be provided with a participant code under which all your data will be collected and stored. The key to the code will be stored separately in a password-protected computer file to which only the study team will have access. At the end of the study (once you have returned all study equipment) and completed all study requirements, the key linking your name and participant code will be deleted, ensuring your data remains anonymous and de-identified for analysis and future use.

Complaints

This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Ethics Coordinator on

+617 3365 3924 or email humanethics@research.uq.edu.au.

Results and Questions

Thank you for considering participation in this research. If you would like further information regarding any aspect of this project, or you would like to be informed of the aggregate findings of the project upon its completion, please contact the Chief Investigator on the contact details provided below.

Thank you,

Dr Shamsi Shekari (Chief Investigator)

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