Participant Information Sheet

People who drive under no illicit drugs nor prescription medication

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 driving performance of people who are not driving under the influence of illicit drugs and/or prescription medication. 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 illicit drugs and/or prescription medication 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. Currently, there is limited evidence for trends or the characteristics of driving impairments in people who drive under the influence of drugs or medications in Australia as well as the sustainability of these impairments. This study aims to provide the baseline data for understanding how using prescription medication and illicit drugs affect people's ability to drive safely.

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)
- Have access to a vehicle during the study.
- Do not use any illicit drugs.
- Do not use any prescribed medicine that causes drowsiness while driving.

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.

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What does the research involve?

This is an experimental study that will only require a small portion of your time. You will be required to attend a one-hour induction session before commencing your participation in the experimental study. The induction session will be conducted via Zoom with your participation starting on the day of the induction session. During the induction session, you will be asked to complete some questionnaires about your general health and sleep quality. The experimental study will run for one week. For the majority of this one week, you will only be asked to complete a short daily sleep diary every morning (that will be emailed to you). However, you will also be required to attend one 1.5-hour laboratory session. It should be reinforced that no prescription medication and or illicit drugs will be given before your participation and you will be tested under your normal driving conditions. The test session will be held at the sleep laboratory in the Institute for Social Science Research (ISSR). ISSR is located on the Long Pocket campus, close to the public transport, and has free parking space.

At the test 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 by attaching two electroencephalography (EEG) electrodes to 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 keeping the eye google on your eyes. To recognise your contribution to this study, the research team is offering a $60 voucher upon completion of the test session.

Study timeline overview

Pre-study Induction session, fill out questionnaires	Arranged time
Life, as usual, filling out the sleep diary	Week 1
Visit ISSR, 1.5-hour	End of week 1

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 name following your exit from the study, ensuring your data remains non-identifiable. Upon written request, you may also withdraw your data. Please be aware that this will only be possible while you are in the study. Withdrawing in any way from the study will have no adverse effects on your relationship with the researchers or the University of Queensland.

Expected benefits

The findings from this study will provide preliminary data to bee compared with data on driver impairments while driving under the influence of illicit drugs and/or prescribed medication. 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:

- 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 foe 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 tasks during the Laboratory Sessions. This risk is minimal. We will ensure that you can take breaks as required, and we will provide 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. Some questionnaire items may ask you about involvement in risky driving. Please note that we will not disclose this information to any third parties.
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.

Storage of data

All research data will be stored securely. Digital research data will be stored on the UQ Research Data Management System. Hard copies of data will be stored securely in locked filing cabinets at UQ. Only researchers associated with this project will have access to the electronic and hard-copy data files. All hard copy and electronic data associated with this project will be stored under the National Statement on Ethical Conduct in Human Research.

Use of data

Data from this project will be used to inform future research projects. Additionally, sometimes it is useful to use your data for research purposes other than those specified in this statement. For example, researchers may think of a new question that your data may help to address. By agreeing to participate in this study, you consent to the use of your data in this way. Please note that your data will only be used in a de-identified format, ensuring your anonymity. Findings from the study may be submitted for publication in peer-reviewed journals and/or presented at academic conferences. Please note that only aggregated and de-identified data will be presented, ensuring the non-identification of individual participants.

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,
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