Choosing safer vehicles and increasing the competency and confidence of older drivers in the use of advanced vehicle technologies

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Contents

1. BACKGROUND

1.1. BACKGROUND

Older drivers in Australia drive older cars[1], have increased crash involvement particularly intersection crashes[2] and are more vulnerable to injuries[3]. Driving is a treasured skill for older Australian adults who rate driving as the second most important activity of daily living[4]. Unfortunately, age-related declines in visual, cognitive and physical skills, all negatively influence driving performance, making older drivers one of the most vulnerable road users. These declines, alongside increased frailty and fragility associated with ageing, increase the likelihood of serious injuries or death in a motor vehicle crash[5]. Older drivers struggle more with common driving manoeuvres such as gap perception, hazard recognition and avoidance, and intersection navigation. In the twelve months to August 2021, there have been 222 road fatalities amongst persons aged over 65 years[6], and more than 5000 individuals hospitalised in 2017 alone with this figure expected to rise with the ageing driving population[7]. Hospitalised older drivers also spend on average longer times in care with more intensive treatment than young and middle-aged drivers.

Autonomous Vehicle Technology (AVT), such as crash avoidance systems, in-vehicle information systems, and comfort-supporting systems, are available in a range of vehicles including mid-range price vehicles and are likely to become standard[8].They have been shown to promote and enhance safe driving[8, 9] whilst potentially mitigating age-related declines[10]. However, when purchasing a new car, drivers often have a superficial understanding on the capabilities of AVTs[9]. In addition, there is limited research investigating AVT for older drivers specifically. A recent scoping review found <10% of studies examining AVT examined use by older drivers[8]. Further, very little is still known about how older drivers view these technologies, their convenience and the ability of older drivers to use them correctly in order to continue safely driving[10]. Education and training programs for AVTs are not routine other than instructions at point of sale, reading the vehicle manual, or through trial and error[9].

The limited evidence to date has shown low usage, awareness, confidence, and competency levels of these safety features amongst older drivers[11-13]. This may be due to a combination of high self-rated driving confidence in older drivers and the fact that many older drivers use older vehicles which do not feature AVT. The average vehicle fleet in Australia increased to 10.4 years (2020) with just over 14% of all passenger vehicles manufactured before 2002 still in use[14]. When looking at select LGAs with higher proportions of older adults than the national average, the age of vehicles driven in these areas are also older in comparison to other areas. The low exposure to AVTs may explain why older drivers have shown mixed attitudes towards the supposed safety benefits of these technologies, with many older adults prioritising other car features, such as price and fuel efficiency, when purchasing new vehicles[15, 16]. Studies have shown that compared to no training, any type of training in AVT use is beneficial to driving performance. Training programs for older drivers in the use of AVT, need to be designed with careful consideration of how older people engage and learn about new technology.

1.2. RATIONALE FOR PERFORMING THE STUDY

This project aims to reduce road traffic injuries and fatalities by increasing awareness and use of newer cars with available AVT: Level 0 (warnings and alerts) and Level 1 (driver assistance) and Level 2 (adaptive cruise control and lane keeping assist). This trial builds on a successful pilot study (n=8) of a multi-modal training program involving 1) an interactive classroom session, and 2) an on-road (naturalistic) driving session with a licensed driving instructor (DI) or Occupational Therapy Driving Assessor (OTDA) in a dual-controlled vehicle, developed through an expert panel review process led by the research team in 2019-2020. This project will comprehensively investigate AVT for today's older

drivers, with findings of relevance to consumers, insurers, and policy makers to understand how to position AVTs to enhance the safety older drivers.

2. STUDY OBJECTIVES

This study will determine whether the innovative training program will increase driving competence and confidence of older Australians driving vehicles with currently available AVTs (Level 0-2).

1. Primary outcome: assessor-blinded, in-vehicle assessment of on-road driving performance (test score) and on-road competence on AVT use (test score)
2. Secondary outcome: vehicle damage (inspection), driving confidence (standardised questionnaire), self-reported crash involvement (count), and perceived competence on AVT use (test score)

3. STUDY DESIGN

3.1. DESIGN

This RCT will take place in urban and regional New South Wales Australia, coordinated by the School of Optometry and Vision Science at UNSW. This study is an assessor-blinded, two-group, randomised controlled trial (RCT). The statistician will be blinded to group allocation. It will not be possible to blind the participants due to the nature of the intervention.

3.2. STUDY GROUPS

This RCT will include older Australian drivers, aged 70 years and over.

3.3. SAMPLE SIZE / NUMBER OF PARTICIPANTS

Building on the development and pilot testing of this training program, a study of approximately 100 older drivers will be required to evaluate the impact of the training program on driving performance. This sample size will have >90% power to measure a meaningful difference in driving safety (1.5 points on a 0-10 scale) with 5% level of significance, based on the distribution of scores in a population of older drivers in Australia on average 76 years of age[17]. A total of 120 older drivers will be randomised to allow for 15% dropout, and will be randomly allocated to the intervention or control in a 50:50 ratio.

3.4. NUMBER OF CENTRES

Site	**Address**	**Contact Person**	**Phone**	**Email**
The Institute of Driver Health	PO Box 6570 Rouse Hill NSW 2155	Joan O'Donnell	1800 348 237	joan@driverhealth.com.au
Driving Assessment and Rehabilitation Service	80 Hills Street Port Macquarie NSW 2444	Nick Neville	(02) 6583 6789	nick.neville@prosm.com.au

Each site will randomise approximately 60 subjects to achieve the desired sample size. Each site will follow the same study procedure, and have multiple local organisations facilitate recruitment following the same recruitment strategy.

3.5. DURATION

This RCT will occur over a period of 18 months. Participants will be recruited over a period of 12 months, from February 2022 to February 2023.

4. PARTICIPANT SECTION

4.1. INCLUSION CRITERIA

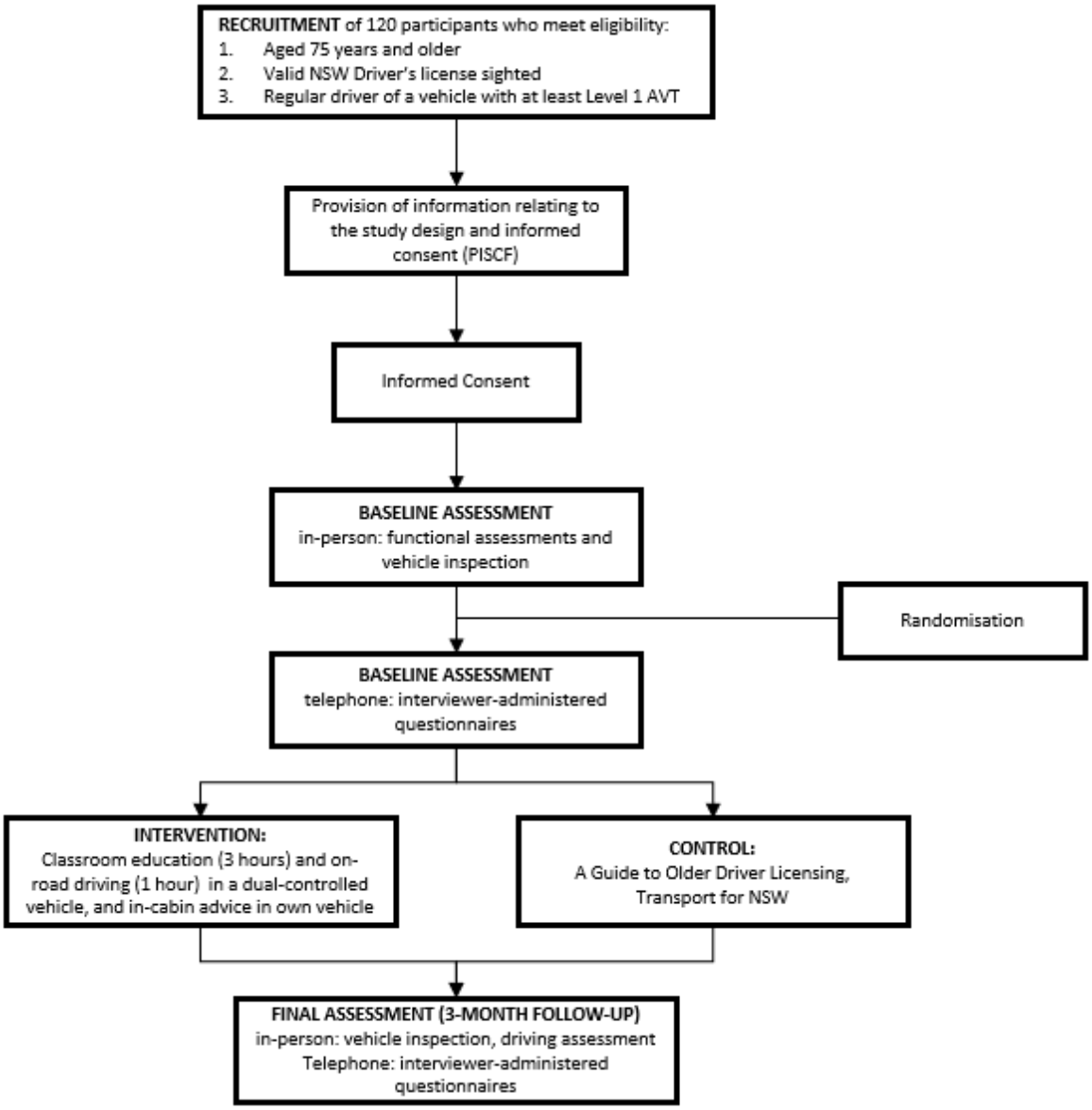
1. Aged 70 years and older
2. Has an active and valid NSW Driver's license (Class C)
3. Regular driver (at least 2-3 times per week) of a vehicle with at least Level 1 AVT (driver assistance such as collision or lane departure warnings, lane keep assist, cruise control)
4. Able to travel to sites/driving centres for study visits
5. Consent to use your personal vehicle to perform a driving assessment in the presence of a Occupational Therapy Driving Assessor (OTDA) and/or licensed driving instructor (DI)
6. Consent to drive an unfamiliar vehicle
7. Able to meet the time commitment of the study (approx. 3.5 to 7.5 hours across several days)
8. Able to understand conversational English

4.2. EXCLUSION CRITERIA

1. Has a modified driver license which restricts attendance or completion of study activities, e.g. can only travel restricted distances from home by which the study sites or driving assessment route is not included

5.STUDY OUTLINE

5.1. STUDY FLOW CHART



5.2. INVESTIGATION PLAN

Screening Assessment

Upon expression of interest into the study, participants will be screened for their eligibility over the phone. This will involve determining whether participants meet inclusion/exclusion criteria. Verbal consent will be obtained for the screening process. Names and contact details (email, phone number, address) will also be collected to contact eligible participants over the course of the project. These will be kept separate to all other data and re-linkable through a participant identification number (PID). The PID will be generated automatically by REDCap and documented on all participant study documents. Screening will take approximately 5-10 minutes.

Baseline Assessment (In-person)

Participants will provide informed consent when they present for baseline assessment prior to any data collection. Participants will complete a standard battery of functional assessments (vision, physical and cognitive) with a OTDA, and have their vehicle inspected for any damages by either a licensed DI or OTDA. This will take approximately 1 hour.

Randomisation

After baseline assessment, a computer-generated allocation sequence will be used to allocate participants to either the intervention or control arm of the study. The allocation sequence will be prepared using a blocked randomisation model by a researcher with no involvement in the trial and uploaded to REDCap.

- Intervention arm: Participants will partake in the training program involving the interactive classroom and on-road driving sessions with a licensed DI or OTDA, in a dual-controlled vehicle.
- Control arm: Participants will be provided with information about driver licensing in NSW (A Guide to Older Driver Licensing, Transport for NSW)[18].

Baseline Assessment (Telephone Interviews)

Participants will complete interviewer-administered questionnaires on socio-demographic characteristics, driving confidence, perceived AVT competence, and self-reported crashes. This will take approximately 40 minutes and occur over the phone with a research assistant, within one week of the in-person baseline assessment.

Intervention

Participants randomised to the intervention group will firstly participate in an interactive classroom education session, led by a licensed DI or OTDA, aiming to familiarise older drivers with AVT, their benefits and correct use, in groups of 8 to 10 older drivers per session. Classroom training will run for a total of 3 hours, including 30 minutes for morning tea, and will involve input from an older driver already using AVT, and the use of handouts, pamphlets and audio-visual material such as video and photographs. Topics discussed include:

1. Ageing and driving – what to look out for
2. Autonomous Vehicle Technology – what are they, and what functions do they perform?
3. Autonomous Vehicle Technology – benefits to drivers?

4. Autonomous Vehicle Technology – risks to drivers?

On a separate day, each participant will be scheduled to complete a 1-hour practical, on-road (naturalistic) training session with a licensed DI or OTDA to implement their new knowledge and skills from the classroom education session. This will occur in the local area of the study sites. One hour is considered sufficient timing to experience the range of AVT fitted into the provided dual-controlled vehicle, such as lane departure warnings, road sign recognition and navigation aid. Each on-road driving session will involve on-road instruction in AVT use, demonstration of route prior to participant driving, and broken into three parts:

1. Participant driving on a pre-planned route designed to demonstrate the AVT on board the provided vehicle. For example, narrow and winding roads are more likely to activate lane departure alerts, multiple speed zone changes will result in an alert that the speed zone has changed and a highway section that will demonstrate the following distance of the vehicle, relative to the vehicles in front. This will involve an increase in complexity, where the route will start in an area of low traffic density and move into areas of moderate traffic density.
2. A navigation task using the navigation aid will involve participants being asked to navigate to and from one unfamiliar location to another.
3. A reverse maneuver using a reverse camera and proximity alerts. This task will be performed in a traffic free environment. The design of this task has been informed by the literature on drivers experience with rear parking sensors and will involve the following:
    a. Reversing towards an object that cannot be seen in the rear-view mirror
    b. Reversing into an area towards an object that can be seen in the rear-view mirror (reverse park)

Further in-cabin advice in the participant's own vehicle will also be provided.

Table 1: Description of the educational program on autonomous vehicle technology (AVT) for older drivers using the template for intervention description and replication (TIDieR) checklist and guide

Why	This program was developed through an expert panel review process to increase older driver awareness and use of available AVT, thereby reducing road traffic injuries and fatalities.
What	Materials: a program manual is provided to all licensed DIs or OTDAs. Participants are provided presentation slides, hand-outs, pamphlets, and audio-visual material on educational materials. A dual-controlled vehicle will be provided. Procedures: participants first attend a group classroom session on AVTs and their benefits, risks and correct use. Participants then attend an individual driving session with on-road driving instructions in AVT use in a dual-controlled vehicle.
Who provided	OTDAs and/or licensed DIs
How	Face-to-face in groups of 8-10 for the classroom session, and individually for the on-road driving session
Where	Classroom sessions: an accessible local venue near study sites. On-road driving sessions: on a local pre-planned 20km route designed to demonstrate AVT on board a dual-controlled vehicle
When and how much	Two sessions in total; one 3-hour classroom session, and one 1-hour long on-road driving session
Tailoring	Participants will receive advice on AVTs available in their own vehicle

Modifications	No modifications have been made
How well	This educational program was piloted and assessed with positive reception from a small group of older drivers in Port Macquarie.

Control

Participants randomised to the control group will receive information about older driver licensing in NSW, "A Guide to Older Driver Licensing" by Transport for NSW. A hard copy will be provided to participants at the end of their in-person baseline assessment. At the end of the study, participants will have the option to attend classroom sessions of the training program.

3-month follow-up (in-person)

All study participants will have their driving performance assessed 3 months after randomisation in their own vehicle, through a 40-minute, standardised, on-road driving assessment (Performance Analysis of Driving Ability, P-Drive)[19] by a driving assessor blinded to group allocation. The driving assessor will be separate from those involved in the intervention arm. Participant vehicle will also be re-inspected for damages.

3-month follow-up (Telephone Interview)

Interviewer-administered questionnaires on driving confidence and perceived AVT competence will be re-administered and self-reported crashes re-documented, over the phone. This will occur within one week of the in-person 3-month follow-up.

Table 2: Summary table of study visits and procedures in sequential order

Variable (measure)	**Baseline Assessment**	**3-month Follow Up**	**Outcome**
Vision[20]	x		
Physical [21-26]	x		
Cognitive (DriveSafe DriveAware)[27]	x		
Vehicle inspection	x	x	S
Socio-demographic Questionnaire	x		
Self-reported driving confidence[28, 29] and crashes[30]	x	x	S
Self-reported AVT competence	x	x	S
Driving performance (P-Drive)[19, 31]		x	P
AVT competence		x	P

AVT, autonomous vehicle technology; P-Drive, Performance Analysis of Driving Ability; P, primary outcome; S, secondary outcome

5.3. Study Procedure Risks

The perceived benefits from the intervention outweigh the potential risks. Participants will be informed clearly about the educational process and learning opportunity involved in this study and of any potential risks to their health and safety. OTDA and licensed DIs are highly skilled in driver instruction and working on-road with drivers of varying ability, and will use a dual controlled car in the training program. Participants randomised to the control group will not be disadvantaged when participating in this study as they will continue life as usual and receive a guide on older driver licensing by Transport for NSW.[18] Participants in the control group will be invited to attend an optional classroom session of the training program, at the end of the study.

A list of identified risks or discomforts associated with trial interventions, and strategies to mitigate or manage them is shown below.

Table 3: Identified risks and mitigation strategies

Risk	**Strategies to mitigate/manage risk**
Researchers become aware of a health condition or visual, physical or cognitive deficits that may negatively impact the participant	A OTDA will write and provide a report for the participant to take to an appropriate health professional, e.g. GP or optometrist. The participant will be withdrawn from the trial.
Participant experiences discomfort or distress in completing assessments or questionnaires.	Researchers will allow the participant to rest and will not continue with the questionnaire or assessment until the participant indicates they are ready to continue. Participants may request to skip questions. OTDAs and licensed DIs can provide appropriate reassurance and emotional support when needed. Participants are able to discuss any concerns or questions throughout any time of the sessions.
Drivers equate involvement in the intervention (classroom and on-road driving session) to direct improvement in their driving skills, regardless of any actual improvement.	The classroom session covers risks associated with AVT use for drivers, such as over reliance on the technology and the potential for deskilling over time. It will be explained that AVTs are designed to only provide drivers with assistance and are not 100% reliable in all circumstances – AVTs do not remove the driver's responsibility to remain alert at all times and response appropriately to traffic situations.
Researchers become aware of driver incompetence that would present a risk to themselves and others	- A OTDA and/or licensed DI will be present to ensure the safety of the participant - A pre-planned route will be used and designed to gradually increase difficulty throughout the session. It will avoid areas such as school zones and busy pedestrian areas. The licensed DI/OTDA will demonstrate the route prior to participants being allowed to drive. - The vehicle being used will have dual-control brakes where a licensed DI or OTDA can apply the brakes from the passenger seat.

	- If the OTDA and/or licensed DI rates driver incompetence as high, they will stop the session and return to the study site (the participant will not be the driver). A report will be provided for the participant to take to the relevant health professional.
Driving an unfamiliar vehicle on public roads amongst other road users, pedestrians, and traffic.	- All participants will be provided with a PISCF to understand the nature of the project and any potential risks to their health and safety, with participants ensured that they can withdraw at any time. Participants must provide informed consent to confirm they have read the PISCF and understand potential risks involved. - All participants will be English speaking, licensed Class C drivers, and own a vehicle with at least Level 1 AVT (driver assistance) - The classroom education content will familiarise participants with a range of AVT prior to the on-road driving session where the potentially unfamiliar car will be used. - A licensed DI or OTDA will be present to ensure safety of the participant. - The vehicle being used will have dual-control brakes where a licensed DI or OTDA can apply the brakes from the passenger seat.
Participants may be using unfamiliar technology which may cause distractions from the driving task and thereby increasing risk of crash.	Various strategies will be adopted to reduce this risk, including: - Time of day: the on-road driving session will only be conducted during daylight hours and off-peak traffic conditions (e.g. avoid school drop off and pick up times) - Weather: the on-road driving session will not occur in unfavourable weather – defined as excessively windy, rainy, or stormy weather. Any planned on-road sessions will be postponed if the weather is deemed unfavourable. - Route: a pre-planned route will be used and designed to gradually increase difficulty throughout the session. It will avoid areas such as school zones and busy pedestrian areas. The licensed DI/OTDA will demonstrate the test route prior to participants being allowed to drive. - Vehicle: the vehicle used will have dual-control brakes and have a high visibility roof sign. The vehicle has a 5-star ANCAP safety rating, is comprehensively insured, and registered for business use as an instructor's vehicle. - Phone and first aid kit will be carried in case of emergency
Road Accidents in dual-controlled vehicle	At the site, the OTDA/Licensed DI will render first aid / call emergency services as needed then collect details of those involved. An incident report will be completed and sent to the PII insurance company in case of any future claim for person or

	property damage. The separate car insurance company will also be notified and a claim put in for any vehicle damage repairs. Any personal injury to OTDA/licensed DI or participant would fall under CTP insurance, and the study sites also have workers compensation policy for injured workers. Study investigators will be notified.

5.3.1. INSURANCE

Dual-controlled study vehicles will have standard CTP insurance as part of vehicle registration that will also cover injury in the case of accident. Additionally, OT services have mandatory insurance requirements under AHPRA including professional indemnity insurance.

5.3.2. ADVERSE INCIDENTS

Adverse events/reactions and serious adverse events/reactions are assessed using the safety monitoring flow chart. Those classified as not serious must be reported to the project manager within 72 hours of the event occurring while those classified as serious must be reported to the project manager within 48 hours of the event occurring. The project manager will assess the reports in seriousness, causality, and expectedness of the event to the trial design and discuss with investigators at monthly meetings, and if needed, in an earlier timeframe. The project manager will report any adverse event or incident to UNSW HREC as soon as possible after becoming aware of the event, up to a maximum of 7 days.

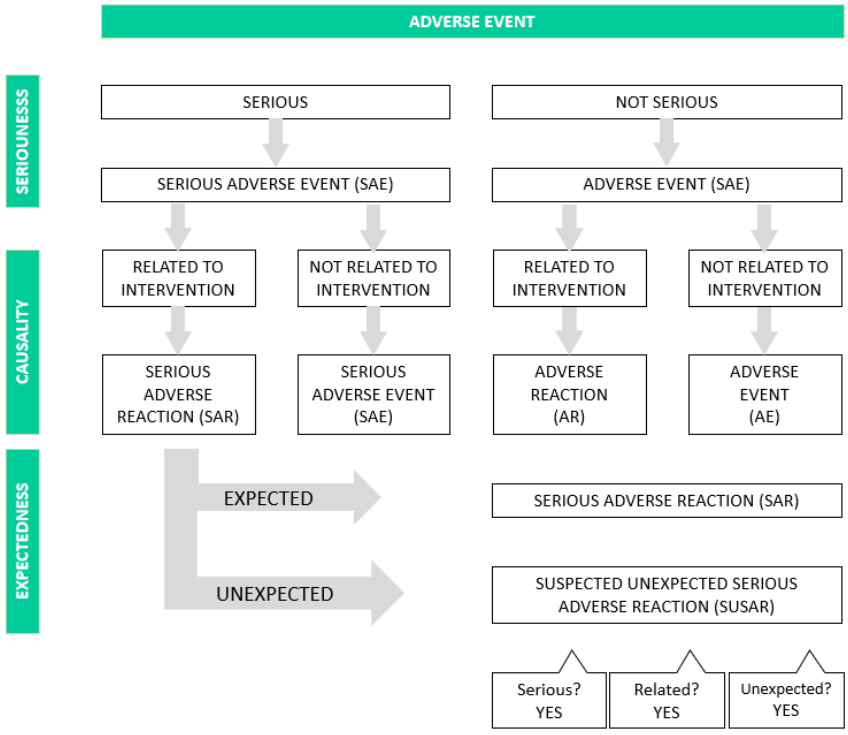
In the case of fatal or life-threatening serious unexpected serious adverse reactions (SUSAR), the event will be reported to the project manager, chief investigator, the sponsor and the approving HREC within 7 calendar days after being made aware of the case, with follow-up information reported within a

further 8 calendar days. All incidents will be recorded in the UNSW Safety Monitoring Register and will be reported annually to the approving HREC and sponsor.

Definitions of adverse incidents:

- Adverse events (AE): any untoward medical occurrence in a patient or clinical trial participant administered the intervention, which does not necessarily have a causal relationship with the intervention
- Adverse reaction (AR): any untoward and unintended responses to the trial intervention related to any intervention procedures
- Serious adverse events (SAE): any AE that result in or lead to one or more of the following and the event is not related to the trial intervention:
    - Death of a trial participant
    - Life-threatening illness or injury involving a trial participant
    - Participant's permanent impairment of body structure of body function
    - In-patient or prolonged hospitalisation (not for a pre-existing condition or an elective surgery) of a trial participant
    - Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or function of a trial participant
- Serious adverse reactions (SAR): any SAE that is related to the trial intervention
    - Expected SAR: a SAR by its nature, incidence, severity, or outcome is anticipated and identified in the current version of the intervention safety/risk information
    - Suspected Unexpected Serious Adverse Reaction (SUSAR): a SAR by its nature, incidence, severity, or outcome is unanticipated and not identified in the current version of the intervention safety/risk information

Safety Assessment Flow Chart



5.4. RECRUITMENT

Local organisations (e.g. Lions, Rotary, Leisure centre, churches, community groups, medical centres), motoring organisations and car dealerships in Metropolitan Sydney and Port Macquarie will be asked to facilitate recruitment. Permission and rules regarding specific COVID-19 guidelines at each recruitment site will be sought before study advertisements are distributed and recruitment begins.

Organisations will be asked to distribute recruitment material to their members through flyers, newsletter, or email, with instructions on how to contact the research team for further information. Flyers will be posted around the organisation's or dealership's building and include a QR code/link to the PISCF. Newsletters and emails will include a copy of the PISCF via link or as an attachment. All recruitment materials will clearly state that study participation, or non-participation, will not affect their relationship with any of the organisations involved. Snowball recruitment will also be used.

Once potential participants indicate their interest by contacting research team members, they will be given a participant information sheet and consent form (PISCF) via post or email. Participants will have sufficient time to read through this information and consider their participation as they will be instructed to confirm their interest to research team members when ready. Once confirmation of interest is received, the participant will be scheduled for baseline assessment.

Reminders

Recruitment flyers will be available and visible at local organisations and dealerships until the target sample size is achieved. Reminders in newsletters will be circulated according to the local organisation's newsletter distribution timeline.

In absence of a response to initial post or email contact, up to 2 reminder emails or phone calls will be used to follow-up interest in study participation. When participants indicate their interest or non-interest in participation, they will receive no further communications regarding the study.

5.5. INFORMED CONSENT PROCESS

Verbal consent will be obtained to screen participants against the inclusion/exclusion criteria. This will occur when the participant expresses interest in participating in the study by contact the research team member. A copy of the study PISCF will be made available to participants prior to screening through recruitment materials.

Electronic consent on REDCap will be obtained in-person when participants present for baseline assessment. Research team members will ensure participants have read through the participant information sheet and answer any questions before participants provide consent. This will ensure informed consent.

Electronic consent is appropriate as participants will meet research team members in-person to complete the baseline assessments. Research team members will not collect data from participants until informed consent is provided.

5.6. WITHDRAWAL OF CONSENT OR PARTICIPANT PROCESS

Participants will be able to withdraw their consent by contacting research team members through contact details provided in the PISCF. It will be made clear that their decision to withdraw will not affect their relationship with any of the organisations involved.

No further data will be collected from the participant and requests to delete all data collected from them can be made. Efforts will be made to replace the lost participant, recruiting from the same location (South-Western Sydney or Port Macquarie)

6. STATISTICAL CONSIDERATIONS

The outcome measures will be compared between groups using linear regression for the continuous outcomes. Continuous outcomes include the dual primary outcomes, on-road driving performance and competence on AVT use, and secondary outcomes, self-reported driving confidence and perceived AVT competence. Count data (secondary outcomes, vehicle damage and crash involvement) will be analysed using negative binomial regression models. All analyses will be on an intent to treat basis and will be reported in line with the consort statement.

7. DATA MANAGEMENT AND STORAGE

All participants will be assigned a participant identification (PID) number which will be used to link all study-related documents at different stages. This will be generated automatically by REDCap. Personal identifiers such as name and contact details will be collected to contact eligible participants throughout the project, kept separate from research data and re-linkable by PID.

Data will be collected through case report forms on REDCap, a secure web-based server hosted at UNSW, with access limited to research personnel involved in the study. In case of failure of the electronic database preventing data entry, paper-based measures will be used. These will be kept in a locked cabinet of on-site research personnel until they can be entered into the electronic database and will subsequently be destroyed. Any downloaded data will be password-protected, and stored on a secure server at UNSW, UNSW Share Drive, with access limited to research personnel.

Data will be stored for a period of 7 years after project completion, after which, documents deleted and destroyed.

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