Pre-driver Theatre and Workshop Education Research: Cluster randomised controlled trials to evaluate the impact of two interventions on the road safety supportive intentions of 16-18 year old pre-and novice drivers

Abstract

Introduction: Pre-driver road safety education programmes are rarely effective, despite the importance of improving road safety amongst this at risk group and the popularity of interventions targeting pre-drivers. This trial seeks to evaluate two different interventions using a robust cluster randomised controlled trial study design. The Pre-Driver Theatre and Workshop Education Research (PdTWER) study is assessing whether either of the two interventions being trialled can improve pre-driver and newly qualified driver attitudes and intentions.

Methods and analysis: Two interventions are being evaluated, both of which are being delivered to 16-18 year old pre-drivers and newly qualified drivers in schools/colleges within Surrey and Devon, UK**.** For the first intervention, DriveFit, a school/college-based cluster randomised controlled trial (cRCT) is being conducted within government-funded, non-free paying (state), all-ability, co-educational schools /colleges in Devon. Fifty-six schools/colleges in Devon will be sent a recruitment letter in July 2021, with details of how to take part in the trial. Following recruitment, baseline survey measurements will take place in September 2021, with schools/colleges randomly allocated, using a stratified random sampling approach (based on school type and deprivation levels) to one of two conditions: (1) to deliver the DriveFit intervention to 90 year 12 and/or 13 students (3 classes) in each school /college or (2) no-treatment wait list control group. The DriveFit intervention will run in schools /colleges between 1st Nov and 10th Dec 2021. A 40 minute film will be shown in classrooms followed by a 45-minute online facilitated workshop within 2 weeks of watching the film. The film has been designed in the style of a talk show with positively framed messages, where expert guests provide information, demonstrations, and tips about how pre, learner and newly qualified drivers can manage the learning to drive process as well as speeding, tiredness, mobile phone use and intoxicated driving. The film is designed with reference to the Theory of Planned Behaviour (TPB) (Ajzen, 1985) and Behaviour Change Techniques (BCTs) (Michie et al., 2013). The online facilitated workshop which follows the film uses the ORID framework (ICA-UK, 2014) to encourage student to remember the film and extract relevant learning for their own personal situations. Students will be introduced to setting implementation intentions (if-then plans) (Gollwitzer, 1999; Gollwitzer and Sheeran, 2006; Sheeran and Orbell, 1999; Webb and Sheeran, 2006), which they will be invited to commit to DriveFit postcards to take away with them at the end of the session. A website (www.drivefit. info) will support the programme, providing additional information to both students, parents and guardians. In addition to participant data collection at baseline (T1), data is being collected immediately after (T2) and 4-6 weeks after intervention delivery (T3). Participating schools and colleges will be offered a £200 cash incentive for taking part in the trial.

For the second intervention, Safe Drive Stay Alive (SDSA) Surrey, a school/college-based cluster randomised controlled trial (cRCT) is being conducted within government-funded, non-free paying (state), all-ability, co-educational schools /colleges in Surrey. Fifty-three schools/colleges in Surrey will be sent a recruitment letter in July 2021 with details of how to take part in the trial. Following recruitment, baseline survey measurements will be taken in September 2021 ahead of intervention delivery between 1st Nov and 10th Dec 2021. SDSA Surrey consists of a 60 minute film shown in classrooms to students. The film provides negatively framed testimonials from emergency services, bereaved family members and road traffic collision victims which emphasise the consequences of poor road safety behaviours. In addition to participant data collection at baseline (T1), data will be

collected immediately after students watch the film (T2) and 4-6 weeks after intervention delivery (T3). Participating schools and colleges will be offered a £200 cash incentive for taking part in the trial.

For both interventions, the primary outcome will be follow-up adjusted for baseline in a composite measure of self-reported intentions related to the learning to drive experience, driving whilst tired, drink and drug driving, speeding, mobile phone use whilst driving and managing peer passenger distractions. The secondary outcomes will be follow-up adjusted for baseline in self-reported attitudes, subjective norms and perceived behavioural control items related to the road safety risks covered as part of the content of the PdTWER interventions.

Ethics and dissemination: Ethical approval for the study has been gained from the Cranfield University Research Ethics Committee (CURES/3733/2018). Given the lack of rigorously evaluated evidence based interventions to date, the paucity of interventions designed in relation to the evidence and the infrequent use of robust research designs for road safety education interventions, this study is expected to add substantially to the limited evidence on pre-driver road safety education effectiveness. The research is being supported by several national level partners including the Department for Transport, the National Fire Chiefs Council, Road Safety GB, The Road Safety Trust, the RAC Foundation and Kent Fire and Rescue Service, who plan to use study findings to inform future decisions about pre-driver education delivery in Great Britain.

Strengths and limitations of this study: The strengths of the PdTWER evaluation study includes the cluster randomised controlled trial design employed, support from national level partners and the development and delivery of an evidence based and theoretically informed intervention. A possible limitation of the study is that, despite a purposive sampling of schools with varied socioeconomic status, it is likely that participants may not be entirely representative of the wider population in Great Britain.

Trial registration number: [Trial registration in process]

Background

Young driver safety

Young driver safety is a global public health concern. Worldwide, RTIs are the leading cause of death for 15-29 year olds, making up 13% of all fatalities within this age group (World Health Organisation, 2017). In the UK, the 15-29-year cohort accounts for 23% of all RTI deaths (World Health Organisation, 2015), even though 17-25 year olds accounting for a much smaller percentage – 7% - of all licence holders (RAC Foundation, 2016). Between 2000 and 2015 RTI deaths for 15-29-year olds reduced by 63%, but despite this improvement, young novice drivers remain at disproportional risk of death and serious injury. Young males are at particular risk, being almost four times more likely than young females to be involved in a killed or seriously injured (KSI) casualty (Ibid.).

Contributory factors in collisions

Over the last twenty years significant research has been conducted to understand why young novice drivers are at a disproportional risk of injury (Rowe et al., 2015). Driver age and experience are key contributors to greater risk taking and collision risk amongst young novice drivers (Curry et al., 2015b; McCartt et al., 2009; O'Brien et al., 2016; Roman et al., 2015). This is particularly true amongst male drivers (Amarasingha and Dissanayake, 2014; Rowe et al., 2015).

During the first six months of unsupervised driving one in eleven new drivers in Great Britain have been found to report a collision (Helman et al., 2017). Novice drivers have an inflated risk of being involved in collisions within the first 36 months of unsupervised driving (Fisher & Dorn, 2017).

Developmental maturity (Johnson and Jones, 2011; Keating, 2007; Keating and Halpern-Felsher, 2008) and consequent problems with impulse control (Hatfield et al., 2017; Steinberg, 2011; Steinberg et al., 2017) is also a contributory factor in risk taking behaviours amongst young novice drivers, leaving young people vulnerable to distraction from peer passengers (Bingham et al., 2016; Buckley et al., 2014; Heck and Carlos, 2008; Steinberg, 2011; Williams, 2003; Williams et al., 2007) and other technological distractions (Buckley et al., 2014). Young drivers are also more susceptible than older age groups to impaired driving caused by alcohol consumption (Keall et al., 2004) and sleep deprivation or tiredness (Carskadon, 2011).

In additional to these individual risk factors, young novice drivers experience gaps in their driving skills which increases crash liability (Gregersen and Bjurulf, 1996). Passing the driving test is not the same as being a skilled and safe driver. Training regimes across the world almost exclusively focus on passing a practical driving test, despite the fact that the validity and reliability of a skills-based driving test has been queried across a number of studies (Brijs et al., 2014; Groeger and Brady, 2004; Maycock, 2002). Alternatively high-order skills (Hatakka et al., 2002) such as hazard perception are amenable to training (Chapman et al., 2002; Horswill et al., 2010; Pollatsek et al., 2006) can in a matter of hours to bring drivers up to the standard of moderately experienced drivers (Mckenna & Crick, 1997).

Intervention effectiveness

Interventions to date have heavily focused on increasing awareness and knowledge of risk taking behaviours, which has not been found to lead to lasting behavioural change (Mayhew et al., 2014), in part due to the recognised 'intention-behaviour' gap (Fylan, 2017; Senserrick & Kinnear, 2017). Training and education interventions have not typically been developed with a theoretical underpinning; and have instead often taken a short-term and a one-size fits all approach to content development (Pressley et al., 2016).

Studies of their effectiveness frequently involve small sample sizes and/or lack control groups (ibid.), often due to a lack of funding (Mayhew et al., 2014). Measuring the effect of education and training programmes is also problematic, because the desired outcome – reduced collisions – are difficult to assess. Education programmes can also, at worst, cause harm through unintended consequences of earlier driving licensure and increased exposure (Beanland et al., 2013; Christie, 2001). Several interventions have been found to be effective at improving young and novice driver safety at the pre-and-post licensing stages (See Table 1)

Table 1: Effective interventions for improving young novice driver safety at the pre-and-post driver licensing stages

Pre-licensing
• Minimum learning period – 12 months (Mayhew et al., 2014; Senserrick & Williams, 2015) • Over 100 hours supervised practice (Cavallo and Oh, 2008) • Varied and many opportunities for practice with family (Groeger and Brady, 2004) • Professional lesson for correcting poor technique and correcting poor techniques (Tronsmoen, 2011) • Hazard perception training – Poor skills are related to collision involvement and experienced drivers score more highly than inexperienced drivers (Horswill and McKenna, 1999; Quimby et al., 1986); with training found to improve skills, in simulated and real-world conditions (Mcdonald et al., 2015; Pradhan et al., 2009)

Post-licensing
• Graduated driver licensing (Depesa et al., 2017; Kinnear et al., 2014; Lyon et al., 2012; Mayhew et al., 2014; Mccartt et al., 2010; Senserrick & Williams, 2015). • Zero-alcohol limit (Keall et al., 2004) • Fatigue management (Owens, 2014) • Vehicle crashworthiness (Keall and Newstead, 2013; Watson et al., 2009; Whelan et al., 2009) • Parental interventions (active approaches using concrete tools – such as parent-teen agreements and IVDR feedback) (Curry et al., 2015a)

Source: Authors own

Road Safety Education

Road Safety Education (RSE) is considered to be an important component of the overall Road Safety System (Senserrick and Kinnear, 2017), with researchers recognising its potential to complement other interventions providing that an evidence-based and theory led approach is adopted (Mayhew, 2007). Research on the effectiveness of RSE over the past twenty years has found that programmes have consistently failed to deliver on their safety objectives, and have not assisted in enhancing protective licensing approaches for young and novice drivers, such as Graduated Driver Licensing (GDL) (Mayhew, 2007). RSE has also had little or no direct effect on the collision risk of new drivers (Helman et al., 2010). It has been recommended that future RSE programmes are based on sound research, theory and linked to behaviour change techniques (Lonero et al., 2010; Pressley et al., 2016).

Pre-driver interventions

Pre-driver interventions typically seek to improve safety by influencing pre-driver attitudes, knowledge and/or skills (Kinnear et al., 2013) during adolescence. Whilst there is good evidence for intervening at this stage (Helman et al., 2013; Mann and Lansdown, 2009; Rowe et al., 2016a), given the short-term effect that interventions of this type have, targeting delivery at the right time for is important (Rowe et al., 2016a).

Evidence on the effectiveness of pre-driver education programmes remains both mixed and limited. Whilst some programmes have been found to influence knowledge and beliefs (Poulter and McKenna, 2010a), this has not typically translated into behaviour change (Bojesen and Rayce, 2020), with programme impacts also influenced by participant gender and educational status. Short term benefits including improvements in attitudes to risk (Cutello et al., 2020b), violations (Feenstra et al., 2014), risk perception and self-efficacy (Lanning et al., 2018) have also been noted.

Whilst some positive effects have been demonstrated, numerous research studies have found no overall effect of the programmes delivered (Bojesen and Rayce, 2020; Dale et al., 2017; Feenstra et al., 2014; Markl, 2016) with several also finding negative outcomes including plausible mechanisms of harm and unintended outcomes. In one study intentions to conform with the Highway Code got significantly worse five months after the intervention, which raises the possibility that road safety education can have counterproductive effects (Poulter and McKenna, 2010b). Other unintended consequences have also been explored by Mayhew et al (1998).

Fear appeal interventions, often delivered through testimonial style performances, are both widespread and controversial. Whilst the health communications literature presents a mixed picture on the impact of fear appeal approaches the prevailing viewpoint amongst behavioural scientists and health promotion professionals is that threat appeals should be used with caution. Threat appeals can attract attention (Lewis et al., 2007), but this does not reliably translate into behaviour change (Carey et al., 2013).

Whilst threat appeals can have an impact, if certain conditions are met , they can provoke an increase in risky behaviours (Carey et al., 2013; Lennon and Rentfro, 2010). Fear appeals are frequently found to be counter-productive for males (Goldenbeld et al., 2008), which can lead to defensive reactions, avoidance of threatening information and message rejection, as evidenced in other areas of public health (Brown and Locker, 2009; Hastings, 2002). Males are also less likely to find the material applicable to themselves (Lewis et al., 2007), which is an important consideration given the prevalence of young male drivers within road safety casualty statistics.

Increasingly positive emotional appeals are being recommended for use. This involves the portrayal and modelling of safe driving behaviours and the positive consequences of adhering to that behaviour. This can include humour, with content that encourages empathy, role-modelling, hope and compassion. Such approaches have been found to be more effective than fear appeals in reducing risky driving behaviours, particularly amongst high risk drivers such as young drivers (Lewis et al., 2008) and can also increase the relevance of and engagement with risk information (Cutello et al., 2020a). How the message is received and processed also matters. Messages that are neither excessively arousing (e.g. fear appeal) or disengaging (e.g. purely factual presentation) have been found to support optimal message processing (Rhodes, 2017).

There is an urgent need for more rigorous evaluation of positively framed, theoretically grounded interventions for pre-drivers, to increase the safety outcomes for this at risk group.

Objectives

The primary aim of this study is to assess the effect of two pre-driver interventions at increasing self-reported positive road safety intentions amongst 16-18 year old pre-drivers and newly qualified drivers over a 6 week period. The effect of the two interventions on the secondary outcomes of self-reported positive road safety attitudes related to other TPB items (attitudes, subjective norms and perceived behavioural control) will also be assessed immediately post intervention. Potential moderation of intervention effects by gender, socioeconomic status and ethnicity will also be investigated. A process evaluation will also be conducted including questionnaires, focus groups and individual interviews (with participants, teachers and intervention facilitators) and from intervention logs.

Interventions

DriveFit

The DriveFit programme consists of a 40 minute film shown in classrooms followed by a 45-minute online facilitated workshop within 2 weeks of watching the film. The film is a positively framed talk show, where expert guests provide information, demonstrations, and tips about how pre, learner and newly qualified drivers can manage the learning to drive process as well as speeding, tiredness, mobile phone use and intoxicated driving. The film is designed with reference to the Theory of Planned Behaviour (TPB) (Ajzen, 1985) and Behaviour Change Techniques (BCTs) (Michie et al., 2013). The online facilitated workshop which follows the film uses the ORID framework (ICA-UK, 2014) to encourage students to remember the film and extract relevant learning for their own personal situations. Students are introduced to setting implementation intentions (if-then plans) (Gollwitzer, 1999; Gollwitzer and Sheeran, 2006; Sheeran and Orbell, 1999; Webb and Sheeran, 2006), which they are invited to commit to DriveFit postcards to take away at the end of the session. A website (www.drivefit. info) supports the programme, providing additional information to both students, parents and guardians.

The logic model for the DriveFit programme is as follows:

Inputs	***Immediate impacts***	***Short-term impacts***	***Behavioural impacts***	***Health Outcomes***
Providing a film and workshop to 16-18 year old students will…	Result in the delivery of the DriveFit programme in intervention schools and colleges which will…	Result in changes to student attitudes and subjective norms towards what it takes to be a good driver and the development of students' self-efficacy and skills for being safe passengers and drivers, which…	will result in safer passenger and driver intentions and behaviours and ultimately,	Reduced deaths and serious injuries amongst this at risk group.

Whilst the health outcome in the logic model will not be specifically measured as part of this research, the logic model is based on previous research, with the meta-analysis by Armitage and Conner (2001) finding a intention–behaviour correlation of r = .47. The behavioural intentions that are being addressed and measured within this trial are those that are related to death and injury amongst young and novice drivers.

Safe Drive Stay Alive Surrey

Safe Drive Stay Alive (SDSA) Surrey consists of a 60 minute film shown in classrooms to students. The film provides negatively framed testimonials from emergency services, bereaved family members and road traffic collision victims which emphasise the consequences of poor road safety behaviours. The film is based on practitioner level experiences and is therefore not designed with reference to any theory of behaviour. The programme has been running for sixteen years, over which time several published (Road Safety Analysis, 2015) and unpublished evaluations have been conducted. Increasingly SDSA Surrey has incorporated messages related to BCTs, but the programme remains, at its core, a fear-based consequence focused presentation.

Methods

Study design

To evaluate the DriveFit programme, a school/college-based cluster randomised controlled trial (cRCT) is being conducted within government-funded, non-free paying (state), all-ability, co-educational schools /colleges in Devon. Fifty-six schools/colleges in Devon will be sent a recruitment letter in July 2021, with details of how to take part in the trial. Following recruitment, baseline measurements will be taken in September 2021, after which schools/colleges will be randomly allocated, using a stratified random sampling approach (based on school type and deprivation levels) to one of two conditions: (1) to deliver the DriveFit intervention to 90 year 12 and/or 13 students (3 classes) in each school /college or (2) no-treatment wait list control group. The DriveFit intervention will run in schools /colleges between 1st Nov – 10th Dec 21.

To evaluate the SDSA Surrey programme, a school/college-based cluster randomised controlled trial (cRCT) will be conducted within government-funded, non-free paying (state), all-ability, co-educational schools /colleges in Surrey. Fifty-three non-free paying (state), all-ability, co-educational schools /colleges in Surrey will be sent a recruitment letter in July 2021 with details of how to take part in the trial. Following recruitment, baseline survey measurements will be taken in September 2021 ahead of intervention delivery between 1st Nov - 10th Dec 21.

For both interventions, in addition to participant data collection at baseline (T1), data will be collected immediately after (T2) and 4-6 weeks after intervention delivery (T3). Participating schools and colleges will be offered a £200 cash incentive for taking part in the trial. The protocol is being conducted and will be reported in accordance with CONSORT 2010 guidelines[1] and Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) guidance[2].

Recruitment procedures

Schools and colleges

Fifty-six government-funded, non-free paying (state), all-ability, co-educational schools /colleges in Devon with a mixture of socioeconomic status, representative of county level variability and fifty-three schools/colleges in Surrey, chosen using the same criteria, will be invited to take part in the study. Head teachers, sixth form and college leaders from all eligible schools will be sent an invitation letter and school information sheet via email. These documents will describe the study procedures (e.g. student recruitment and consent, measurements) and include an electronic link to an information video describing the PdTWER project. A follow-up email to each school/college will be sent in early September 21, after the initial invitation, to confirm their involvement or to secure their consent to participate if a response has not yet been received. Schools/colleges who do not agree to take part will be asked to select the most relevant reason for their refusal from a predetermined list (e.g. lack of interest, lack of time).

Participants

Ninety year 12 and/or year 13 students (16-18 years) in participating schools/colleges will be eligible to participate in study measurements. Non-participating classes in intervention schools/colleges will be offered the opportunity to watch the film at a time convenient to them, without survey measurements. Participants with a disability and/or learning difficulties, as well as those where English requires support will be included in the study due to the inclusive nature of both the DriveFit and SDSA surrey interventions (sub-titled versions available) and to help avoid stigmatisation of any groups within the schools/colleges. No exclusion criteria will be applied.

All participating year 12 and 13 students will receive a participant information sheet and consent form to complete before taking the online baseline survey. Participants will be informed that they can discontinue all or any part of the study (either or both measurements and intervention) at any time, up until two months post intervention, with no impact on their education.

School/college randomisation

For the DriveFit and SDSA cRCTs, schools/colleges will be stratified based on percentage of disadvantaged students (below and above participating school/college median) and type of educational establishment (school or college).

[1] http://www.consort-statement.org/consort-2010
[2] http://www.spirit-statement.org/registry/

Randomisation lists for each stratum will be prepared by an employed consultant, with cRCT expertise, using Excel, after baseline measurements are completed to ensure schools and participants were unaware of their group allocation at baseline. Half of the participating schools/colleges will be randomised to deliver the PdTWER intervention and the other half to a wait list control condition. For measurements after randomisation, it will not be possible to blind participants to randomised allocation as the intervention schools will be receiving a PdTWER intervention. All reasonable steps will be taken to blind the researcher to the intervention conditions ahead of result analysis.

Control condition

The control groups in Devon and Surrey will be wait list control conditions. Control schools/colleges will receive no-treatment or 'usual care' during survey data collection and will then be offered part of the intervention (film only), for students to watch within their classrooms from February 2022.

Data collection

Measurements will be conducted at three time points via an online survey. The primary measure of intervention effectiveness will be follow-up adjusted for baseline in self-reported intentions related to the road safety risks covered by the DriveFit and Safe Drive Stay Alive interventions. The secondary efficacy outcomes will be follow-up adjusted for baseline in self-reported attitudes, subjective norms and perceived behavioural control related to the road safety risks covered by the two interventions. See Annex B & C for details of the measurement sessions for each intervention.

Questionnaires

At each measurement session (T1, T2 & T3), participants will complete an online questionnaire which measures components of The Theory of Planned Behaviour (TPB). The components of the TPB (intentions, attitudes, subjective norms and perceived behavioural control) are being measured using standardised questions from the literature (Conner and Sparkes, 2005; Rowe et al., 2016b). Demographic data (i.e. age, gender, ethnicity, number of cars in a household) and school-level academic performance will also be collected (publicly available[3]).

Process evaluation

The process evaluation examines the action model for both interventions. The process evaluation questions emulate those depicted in Saunders et al (2005) process-evaluation plan to assess the implementation of a targeted health promotion intervention and will also be developed with reference to Medical Research Council guidance for conducting process evaluations of complex interventions (Moore et al., 2015). The process-evaluation plan for the interventions is in Annex A.

[3] https://www.compare-school-performance.service.gov.uk/find-a-school-in-england

Intervention process data will include mixed-method assessment of student, facilitator, teacher and PdTWER Delivery Board experiences and perspectives of intervention delivery, feasibility, acceptance and barriers/facilitators to participation. Reach (e.g. amount of students that participate in the intervention) and dose received (e.g. delivery of intervention) will be established using teacher logs (and facilitator records in the case of the DriveFit intervention). Process evaluation questionnaires will be administered at T2 for students (both intervention and control) as well as for facilitators and teachers in intervention schools. Control participants will be asked to complete process evaluation questions to determine possible contamination. The teacher questionnaire will ask whether the intervention maintains student attention, whether it was fun for the class, whether they thought the programme had any impact on their class's attitudes and feelings of control around the learning to drive and newly licensed driving process, whether it was a lot of work and whether the students found it boring. Teachers will also be asked to write free-text comments regarding suggested improvements. Classroom observation for the workshops delivered as part of the DriveFit intervention will also be conducted for a random sample of intervention schools/colleges to complement other qualitative methods.

DriveFit intervention facilitators will be provided with a logbook to record both intervention delivery dates and any other descriptive notes at T2. Interviews with facilitators for intervention schools will also take place at T2. An interview guide will be developed and updated as new issues and themes emerge and participants will be encouraged to discuss additional issues.

The lead researcher will conduct semi-structured focus groups, using open-ended questions, at T2 with year 12 and year 13 students in all intervention schools/colleges. Participants will be asked via questionnaire whether they would be willing to be contacted to take part in a focus group about the acceptability of the PdTWER programme, which will be conducted during school time, following a topic guide. Approximately 40 students will be randomly selected from those who have stated that they would be willing to take part in a focus group. Each focus group will comprise between 4-8 individuals to identify themes emerging from the data. Students will be purposively sampled to ensure a mix of gender. The focus groups will be recorded and transcribed verbatim, with transcriptions made anonymous. Broad themes will be derived from the transcripts and example quotes selected to represent the data. At T3, additional semi-structured focus groups and interviews with students will explore the maintenance of passenger, learning to drive and/or novice driver behaviours including whether or not participants have maintained a change in their behaviour and why, whether either intervention helped and why or how other factors have helped or hindered their vehicle use behaviours. T2 participants will be reinvited, supplemented by additional students if needed. This will provide the unique opportunity to explore vehicle use related behaviours over time in the context of a trial and to better understand barriers and facilitators to safe vehicle use.

Data management and monitoring

All data will be collected and managed in line with GDPR requirements. Survey data will be collected online via Qualtrics. All data provided will be treated as confidential and will be stored securely. Where data is electronic, it will be held on a secure networked computer systems with at minimum password access. Anonymisation of survey returns and deletion of any personally identifiable data will be conducted once surveys have been joined and analysis of returns completed. A Strategic Partnership Board (SPB) for the project will monitor the trials progress, and the PhD supervisory team and appointed expert advice will monitor and advise on trial conduct. The SPB membership consists of nominated representatives from the following research funding bodies – National Fire Chiefs Council (Chair), RAC Foundation, Road Safety GB and Kent Fire and Rescue Service as well as one of the trial delivery bodies, Surrey Fire and Rescue Service.

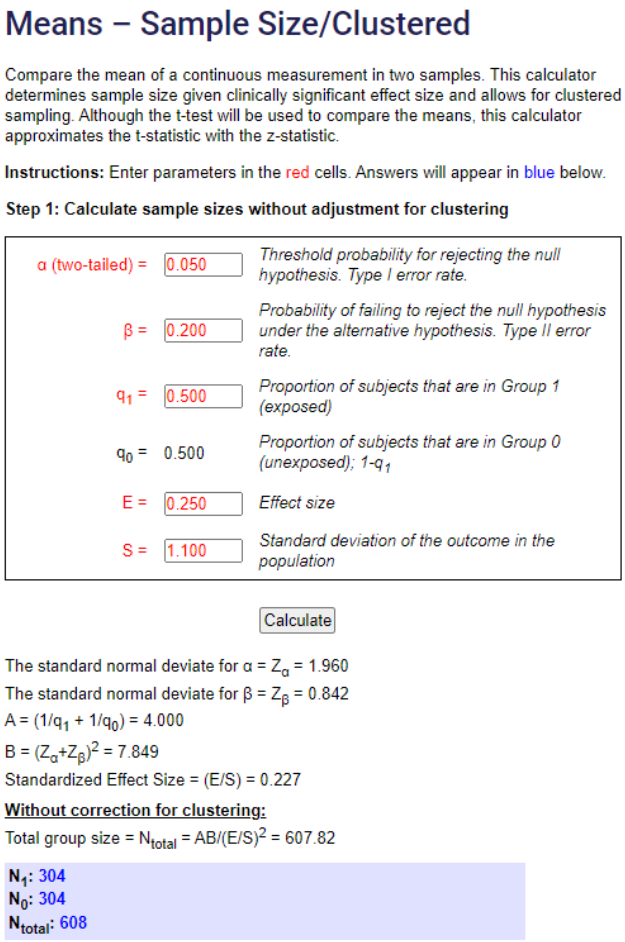
The SPB meets approximately four times per year, or more frequently if required. The SPB is responsible for ensuring the delivery of the project in line with the funding grant agreements and ensuring that the trial is supported by participating Fire and Rescue Service areas. The trial funded facilitators will work closely with the project researcher to monitor protocol adherence. Poor adherence will be discussed with the principal researcher and strategies will be put in place where necessary.

Analyses

Sample size

The aim of the study is to detect differences in mean score follow-up adjusted for baseline in road safety intentions immediately post intervention, and 4-6 weeks after the intervention. To estimate the required sample size, the following parameters have been used: Power = 80%, significance level = 5%, SD = 1.1 (based on a review of Poulter and McKenna (2010) (Range: 1.28-1.68; M = 1.46) and PdTWER studies (Range: 0.6 – 1.45; M = 1.01), intraclass correlation coefficient of 0.05 (Cohen, 1988; Hutchison, 2009; Hutchison and Styles, 2010; Lin et al., 2018) and average cluster size = 60 (two classes within each school).

A trusted online calculator was used (Kohn and Senyak, 2021)[4] to establish the number of participants per group required within a standard RCT, adjusted for a cRCT using the above parameters. The results are as follows:



Means – Sample Size/Clustered

Compare the mean of a continuous measurement in two samples. This calculator determines sample size given clinically significant effect size and allows for clustered sampling. Although the t-test will be used to compare the means, this calculator approximates the t-statistic with the z-statistic.

Instructions: Enter parameters in the red cells. Answers will appear in blue below.

Step 1: Calculate sample sizes without adjustment for clustering

α (two-tailed) =	0.050	*Threshold probability for rejecting the null hypothesis. Type I error rate.*
β =	0.200	*Probability of failing to reject the null hypothesis under the alternative hypothesis. Type II error rate.*
q_1 =	0.500	*Proportion of subjects that are in Group 1 (exposed)*
q_0 =	0.500	*Proportion of subjects that are in Group 0 (unexposed); 1-q_1*
E =	0.250	*Effect size*
S =	1.100	*Standard deviation of the outcome in the population*

Calculate

The standard normal deviate for α = Z_α = 1.960
The standard normal deviate for β = Z_β = 0.842
A = $(1/q_1 + 1/q_0)$ = 4.000
B = $(Z_\alpha+Z_\beta)^2$ = 7.849
Standardized Effect Size = (E/S) = 0.227

Without correction for clustering:

Total group size = N_{total} = AB/$(E/S)^2$ = 607.82

N_1: 304
N_0: 304
N_{total}: 608

[4] https://sample-size.net/means-sample-sizeclustered/

b. Fixed cluster size
With a fixed cluster size, ρ can take any value between 0 and 1.

N_{total} =	607.82	*Total group size (without adjustment)*
q_1 =	0.500	*Proportion of subjects that are in Group 1 (exposed)*
m =	60	*Cluster size*
ρ =	0.05	*Within-cluster correlation coefficient (must be greater than 0 and no greater than 1)*

Calculate

Design Effect = 1+(ρ(m-1)) = 3.95
Clusters in Group 1 = C_1 = N_{total} * Design Effect * q1 / m = 20.01, rounded to 20
Clusters in Group 0 = C_0 = N_{total} * Design Effect * q0 / m = 20.01, rounded to 20

N'_1: 1200
N'_0: 1200
N'_{total}: 2400

Because the formula used here is based on approximating the *t* statistic with a *z* statistic, it will slightly underestimate the sample size when *N* is less than about 30.

Reference:
Donner A, Birkett N, Buck C. *Randomization by cluster. Sample size requirements and analysis.* Am J Epidemiol 1981;114:906-14.

Based on these parameters, for each intervention study a sample of n.students = 2400, n.schools = 40 schools/colleges is sought to achieve primary effectiveness analysis (n = 60 students or two classes per school/college). To account for potential participant drop out, 3 classes (n = 90 students) within each school/college will be asked to take part in the full intervention with measurement. For the DriveFit intervention, fifty-six schools/colleges in Devon will be sent a recruitment letter in July 2021 with details of how to take part in the trial. For the Safe Drive Stay Alive Intervention, fifty-three non-free paying (state), all-ability, co-educational schools /colleges in Surrey will be sent a recruitment letter in July 2021 with details of how to take part in the trial.

Outcome analyses

The primary efficacy outcome, intention, will be compared between intervention and control groups using analysis of covariance, with adjustments made for baseline Intention. Robust standard errors (SE) will be calculated to allow for the non-independence of individuals within each school/college. Where baseline values of intention are missing, the missing indicator method will be used to enable these participants to be included in the analysis (White and Thompson, 2005). An estimate of the intervention effect, 95% CI and p value will be calculated. A similar method will be used for the secondary efficacy outcomes. School-level data will also enable analysis of key differences between those participating in the evaluation and the wider school population; for example patterns of non-response by demographic variables will be explored. Subgroup analysis by prespecified moderators (Gender, ethnicity and baseline road safety support level) will be performed for the primary outcome only. The interaction between randomised group and each moderator will be tested and if the p value is <0.05, the intervention effect (difference between intervention and control, and 95% CI) will be estimated within each subgroup.

The effect on potential mediating variables (attitudes, subjective norms and perceived behavioural control) will initially be assessed in the same way as described above. A formal mediation analyses using the product of coefficient method (MacKinnon et al., 2007) will also be employed.

Qualitative analyses

Focus groups and interviews will be audio recorded, transcribed verbatim and anonymised. Data will be analysed using thematic analysis following a six-phase model (Braun and Clarke, 2006) facilitated by QSR NVivo. Coding will be inductive, incorporating emerging themes as well as topics presented a priori in the interview guide.

Ethics and dissemination

Ethical approval for the conduct of the study has been gained from the Cranfield University Research Ethics Committee (CURES/3733/2018). If successful, it would be appropriate to disseminate this programme to schools and councils across Great Britain (in addition to peer-reviewed publications). Given the lack of rigorously evaluated interventions, the results of this study are expected to add substantially to the limited evidence on pre-driver educational intervention effectiveness. Irrespective of study outcome the evaluation of these two interventions, focused on increasing safe driving intentions in pre-drivers, has the potential to inform the academic literature in this field.

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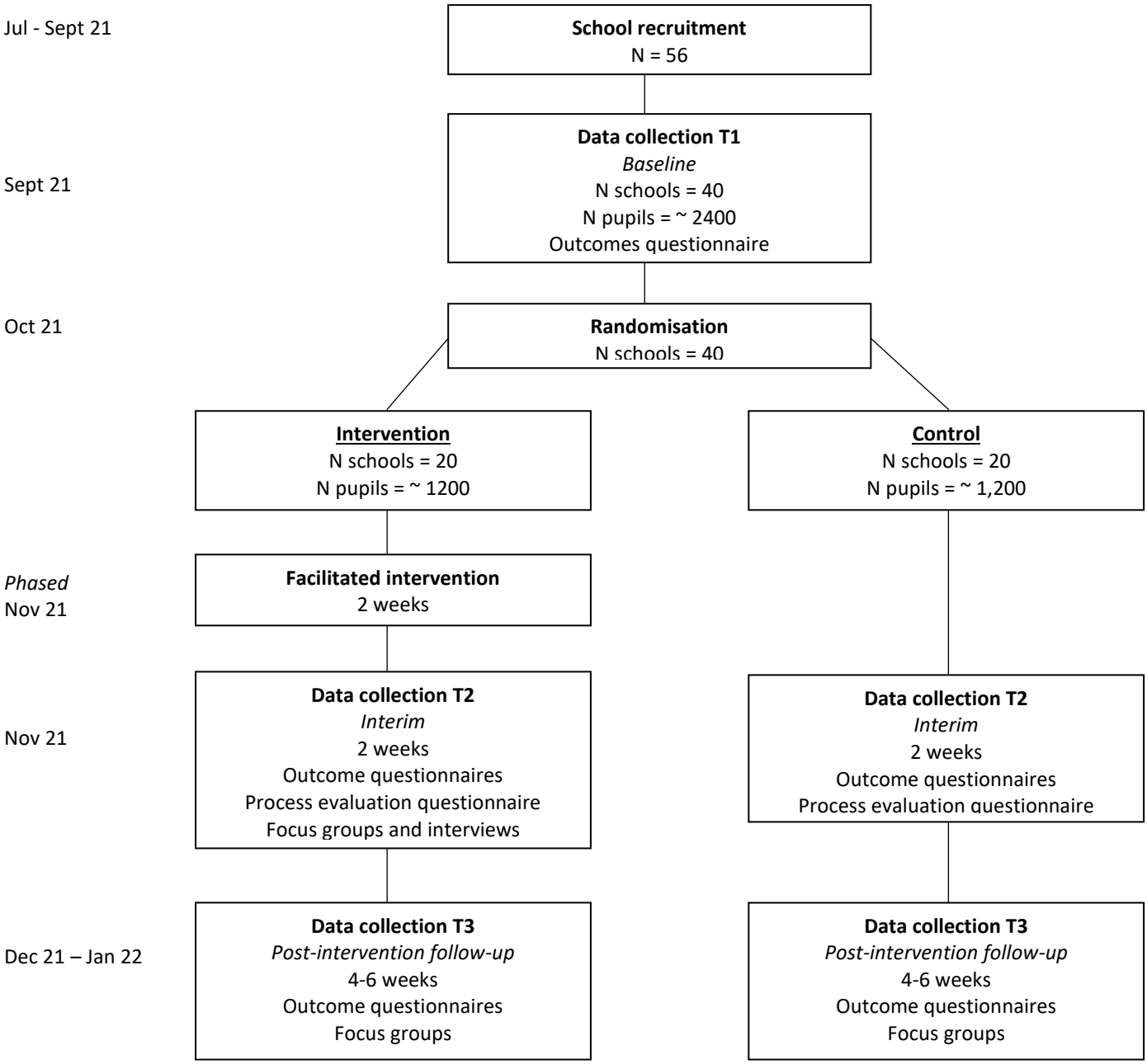
Annex A – Process-Evaluation Plan for PdTWER Intervention

Component	Process evaluation Question	Data Sources	Tools/Procedures
Fidelity	*To what extent was the intervention implemented consistently and as planned?*	- Students - Facilitators - Teachers - PdTWER Delivery Board	Fidelity of implementation will be assessed using an observation procedure. - Google analytics - T2 student website use - Vimeo Analytics – Film downloads by school/college - Workshop Delivery – random sample observation - T2 facilitator logbook - T2 facilitator questionnaire - T2 facilitator focus groups - T2 teacher questionnaire - Field notes - Interview notes - Minutes of meetings - Emails - Reflections - Classroom observations
Dose delivered	*To what extent were the units (film & workshop) within the intervention implemented?*	- Students - Facilitators - Teachers - PdTWER Delivery Board	- Vimeo Analytics – Film downloads by school/college - T2 student questionnaire - T2 student focus groups - T2 teacher questionnaire - T2 facilitator questionnaire - T2 facilitator focus group - T2 facilitator logbook - Intervention observations - Documentation of PdTWER delivery board and facilitator activities
Dose received	*Did students enjoy and engage with the PdTWER intervention?* *Were teachers and facilitators satisfied with the intervention?* *Where the PdTWER delivery board satisfied with the intervention?*	- Students - Facilitators - Teachers - PdTWER Delivery Board	- T2 student website use: Google analytics on frequency and duration of website use - T2 student questionnaire - T2 student focus groups - T2 facilitator questionnaire - T2 facilitator focus groups - T2 facilitator log book

			- T2 teacher questionnaire - Field notes - Interview notes - Minutes of meetings - Emails - Reflections - Classroom observations
Reach	*What % of students within the intervention schools was the programme delivered to?*	- Students	- T2 student questionnaire
Recruitment	*What procedures were followed to recruit schools and participants (students, teachers and facilitators) to the PdTWER intervention?*	- PdTWER Delivery Board - Teachers	- £200 contribution to school/college funds for successful completion of study
Context	*What were the barriers and facilitators to implementing the PdTWER intervention?*	- Students - Facilitators - Teachers - PdTWER Delivery Board	- T2 student questionnaire - T2 student focus group - T2 teacher questionnaire - T2 facilitator logbook - T2 facilitator questionnaire - Field notes - Interview notes - Minutes of meetings - Emails - Reflections - Classroom observations

Annex B – Measurement sessions included in the DriveFit evaluation



Annex C – Measurement sessions included in the Safe Drive Stay Alive Surrey evaluation