STABLE

Slashing Two-wheeled Accidents by Leveraging Eyecare

A stepped-wedge cluster randomized controlled trial to assess the impact of spectacles on reducing crash and near-crash events among motorcycle drivers in Ho Chi Minh City, Vietnam

STUDY AIM

The overall aim of the STABLE trial is to determine whether providing glasses to myopic university students in Vietnam using motorbikes as their primary means of transport will improve their road safety. STABLE will proceed in two phases: pilot and main trial.

OBJECTIVES

Main trial

The objective of the main trial is to assess the impact of providing glasses myopic motorcycle drivers on Crash and Near-Crash (CNC) events, as measured under naturalistic driving conditions with a gyroscopic-sensor-triggered video camera Data Acquisition System (DAS).

Pilot

The objectives of the pilot phase are to:

- demonstrate acceptability of our proposed gyroscopic sensor and video DAS for use on motorcycles in this setting
- create a CNC "dictionary" (range of events) for urban/rural motorcycle riders in Vietnam using our proposed system
- measure event rates in the control (un-intervened) setting, to confirm sample size estimates
- create complete list of financial data needed for cost effectiveness calculations from a societal perspective in the main trial, including cost impact of healthcare, traffic delays, etc.
- confirm 20% rate of uncorrected myopia among students from earlier studies cited above
- assess stakeholder cultural context and attitudes towards motorcycle safety and glasses wear, and design strategy to maximise recruitment and retention.

MAIN STUDY QUESTION

Are young myopic Vietnamese motorcycle drivers at lower risk of crash and near-crash events if they are provided glasses?

SETTING

Ho Chi Minh City, Vietnam.

Pilot

- University of Medicine and Pharmacy at Ho Chi Minh City

Main Trial

- Ho Chi Minh City University of Transport
- Ho Chi Minh City University of Technology
- Ho Chi Minh City University of Science
- Ho Chi Minh City University of Education
- Ho Chi Minh City Nong Lam University

TRIAL DESIGN

Randomised, controlled, step-wedge trial.

PARTICIPANTS

Inclusion criteria: >=1 year driving experience; drives motorcycle > 50 km/wk; male; aged 18-25 years; presenting distance visual acuity < 6/12 in better-seeing eye due to un- or under-corrected myopia<-0.5D, correctable to >= 6/7.5 in both eyes; no other ocular or systemic abnormality affecting driving safety.

SAMPLE SIZE

Pilot Study

The pilot will enrol a single cohort of 175 students, of whom roughly 20% [n=35] will meet myopia eligibility criteria (based on the prior study among Vietnamese university students) in order to create a dictionary of crash-near-crash events using the DAS.

Main trial

The primary aim of this study is to determine whether the intervention can reduce the average number of rear-end CNC events in eligible motorcycle drivers. To inform the power calculation we used preliminary (unpublished) data from Dynamic Vision—currently engaged in the collection of CNC events from motorcycle drivers in Vietnam—to estimate a mean event rate of 1.67 CNCs per 1,000km (SD = 0.556).

It is postulated that a 10% reduction in CNC events is both clinically important and achievable.

The app (https://clusterrcts.shinyapps.io/rshinyapp/) was used to determine the required sample size. A stepped-wedge cohort design with exchangeable correlation structure comprising six sequences (steps) of 5 myopic subjects per cluster, and 5 clusters per sequence, confers 90% power and 95% significance to detect a 10% change in CNC events (mean diff=0.167, SD=0.556) (ICC = 0.02 [0.01-0.05]). This is achieved by fitting DAS for 875 drivers, with 175 assigned to intervention group over the course of the trial, assuming 20% uncorrected myopia prevalence, 5% dropout and 90% glasses-wear compliance.

ENROLMENT AND EXCLUSION CRITERIA

Drivers will be enrolled at participating universities in Ho Chi Minh City in one of five clusters balanced for factors likely associated with crash risk (age, sex, driving history, self-reported distance driven/month). Participants will be asked to use the same motorcycle throughout the study. Size of clusters will depend on the prevalence of myopia (estimated at 20% as noted above, to be confirmed during the pilot) and the baseline and intervention group rates of crashes as assessed in the pilot. All participants will be informed that a forward- and rear-facing video DAS has been fitted to their motorcycles. Participants will be excluded from the trial if they are diagnosed with a non-refractive ocular abnormality.

RANDOMIZATION

Pilot study

In the pilot study, a single cluster will be enrolled to achieve pilot objectives outlined above.

Main trial

A randomisation sequence will be generated using an online random number generator (www.randomization.com) and concealed by password protection on a laptop until the first cluster is ready for randomisation.

Three months after the start of the trial, one cluster will be randomly assigned to the intervention group, and its members will undergo vision assessment, eye examination, refraction and provision of free spectacles providing sphero-cylindrical correction of distance vision for those persons with myopia and vision eligible for study participation.

The remaining clusters will be assigned to continue for the time being in the control group. Every three months a new cluster will be assigned at random to the intervention group and glasses will be provided to eligible persons after examination and refraction.

At the same time, control data from the DAS for the period prior to spectacle provision will be downloaded for these eligible persons, estimated to be 20% of each cluster. Data will not be analysed for those deemed ineligible on the basis of not having under-corrected myopia at the time of the eligibility examination.

After 18 months, all clusters will have been assessed and provided with glasses as necessary and all eligible participants will be in the intervention group, as per the stepped-wedge trial design protocol. In this way, safety data will be obtained from myopic drivers assigned randomly to receive glasses or not, avoiding the ethical conflict of identifying drivers as myopic and having poor vision, but then not providing them with glasses.

MASKING

The investigators feel it is unethical in this setting to mask participants to their allocation status by use of a placebo (glasses of zero power). However, we will mask investigators assessing study outcomes.

MAIN STUDY OUTCOME

CNC events per 1000 km driven as measured by a gyroscopic sensor-video DAS.

CNC events provide the best assessment of driving safety in a setting where motor vehicle crashes often go unreported, and also allows more common near-crash events to be recorded, increasing the statistical power of the main trial to detect an effect.

CNC events are defined as rapid, evasive manoeuvres by the subject vehicle, or any other vehicle, pedestrian, cyclist, or animal to avoid a crash. A rapid, evasive manoeuvre includes a steering, braking, accelerating, or any combination of control inputs that approaches the limits of the vehicle capabilities. Subject vehicle braking > 0.5G or steering input with lateral acceleration greater than 0.4G to avoid a crash generally constitute a rapid manoeuvre.

SECONDARY OUTCOMES

Best-corrected visual acuity and compliance with study glasses; self-reported visual function (driving-adapted Visual Function Questionnaire-25 [VFQ-25]); maximum abbreviated injury score (MAIS) for all crashes; total delivery cost per CNC event avoided in intervention group (indicator of cost-effectiveness).

CAPACITY BUILDING PARTNERSHIPS

ASIA INJURY PREVENTION FOUNDATION

CHEN YET-SEN FAMILY FOUNDATION

DYNAMIC RESEARCH, INC

DTS

HO CHI MINH CITY UNIVERSITY
SCHOOL OF PUBLIC HEALTH
LV PRASAD CLINICAL TRIALS UNIT

ORBIS

NORTHERN IRELAND CLINICAL TRIALS UNIT

QUEEN'S UNIVERSITY BELFAST

TRANSPORT DEVELOPMENT
AND STRATEGY INSTITUTE

TECHNIQUE FOR MEASUREMENT OF MAIN OUTCOME AND SECONDARY OUTCOMES

Use of study glasses will be monitored in the intervention group via driver-facing cameras. Driving safety events will be monitored over the course of the trial using a validated DAS with robust video (forward- and rear-facing panoramic views), kinematic (travelling speed) and geographic (GPS) data collection capabilities. Crash and near-crash events will be monitored through DAS output that will be uploaded to a data processing centre on a regular basis, and will be assessed using data mining algorithms in which kinematic data such as lateral and longitudinal acceleration (e.g. hard braking events, whether the vehicle has capsized, etc.) are passed through filters to discover points at which a CNC event occurred. In the main trial, a Data Monitoring and Ethics Committee (DMEC) will periodically review the summary data from this analysis to assess whether the trial should continue. Main trial closure will occur at the end of the 18-month experiment, unless the DMEC determines that there is evidence to warrant early termination. Study personnel measuring event data will be masked to group assignment.

BASELINE DATA (POTENTIAL PREDICTORS OF OUTCOMES)

Age; sex; years of driving; self-reported number of violations in the last 5 years for speeding, traffic control violations or failure to wear a helmet; contact information; presenting and best corrected distance visual acuity in each eye; contrast sensitivity; ownership of glasses for correction of distance vision, and self-reported regularity of use; measured power of distance refractive error in each eye; results of detailed ocular examination including confrontation fields, pupillary reaction and fundus exam with dilation (ruling out glaucoma or other visually-significant conditions); visual function (VFQ-25).

DESCRIPTION OF ANY QUALITATIVE WORK

Pilot study

A medical anthropologist, who has worked extensively in Vietnam, will meet with stakeholder groups including university students and other young drivers at greatest risk for severe injury, and the Automobile Association of Vietnam. The anthropologist will spearhead a patient and public involvement (PPI) plan (outline below), and will result in the selection of formal PPI representatives to help ensure that both our pilot and full trial fully serve the interests of drivers and their families in Vietnam.

TIMELINE

- Protocol development and approvals: 8 Months (Sept 21 to May 22)
- Recruitment and DAS fitting: 3 Months (May 22 to Aug 23)
- Experiment: 18 months (Aug 23 to Feb 24)
- Analysis and report writing (not including peer review and approval etc): 8 months (Feb 24 to Sept 25)

OUTLINE OF MAIN ANALYSIS

The primary aim of this study is to determine whether the intervention can reduce the average number of rear-end crash-near-crash (CNC) events in eligible motorcycle drivers: that is, does it improve safety for divers.

Analysis will use the generalized linear mixed model, reporting risk differences for binary outcomes and mean differences for continuous outcomes (all adjusting for cluster and time effects). Baseline characteristics will be summarised by their means and standard deviations, medians and inter-quartile ranges, or numbers and percentages as appropriate.

Near crash events will be classified into seven incident types: rear-end, road departure, intersection, head-on, side-swipe, pedestrian/cyclist, and animal. Near crash rates, incident type, secondary tasks, and evasive manoeuvres will be compared across age groups. For rear-end near crashes, near crash severity, maximum deceleration, and time-to-collision at braking will be compared across age. We will also adjust for calendar time, since the intervention will be rolled-out in steps and seasonal factors are likely to play a role in CNC event frequency.

Secondary analysis will adjust for individual and cluster level covariates such as spectacle wear adherence and these will be pre-specified in the Statistical Analysis Plan. Null hypotheses and analyses for secondary outcomes take a similar form to that for the primary outcome. Full details of the analyses will be given in the Statistical Analysis Plan.

An interim analysis will be conducted by the trials DMEC. The interim analysis will be restricted to safety data and the trial's primary outcome (analysed at a higher level of significance).

TRIAL MANAGEMENT AND OVERSIGHT

An independent Data Monitoring and Ethics Committee (DMEC) will been established, whose remit will be to review the trial's progress. The DMEC is independent of the trial organisers. Interim analyses will be supplied, in strict confidence, to the DMEC, as frequently as the Trial Steering Committee (TSC) Chair requests. The DMEC Charter and Operating Procedures will be agreed before their first meeting.

Meetings of the committee will be arranged periodically, as considered appropriate by the TSC Chair. In the light of interim data on the trial's outcomes, adverse event data, accumulating evidence from other trials and any other relevant evidence, the DMEC will inform the TSC if in their view there is evidence beyond reasonable doubt that the data indicate that any part of the protocol under investigation is either clearly indicated or contra-indicated, either for all participants, or for a particular subgroup of trial participants. Unless modification or cessation of the trial is recommended by the DMEC, the TSC, investigators, collaborators and administrative staff will remain ignorant of the results of the interim analysis. The accumulating trial data by step and interim analyses will be confidential and will only be viewed by the TSC upon the recommendation of the DMEC. The TSC will not be routinely privy to these interim reports. The DMEC will make recommendations to the TSC based on the interim data.

Collaborators and all others associated with the study may write to the DMEC to draw attention to any concern they may have about the possibility of harm arising from the treatment under study. The TSC Charter and its relationship to the DMEC will be discussed and agreed prior to the start of recruitment.

ENGINE
VISION DRIVES DEVELOPMENT

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