The effect of visual patient education on helmet use behaviour in elderly patients after a bicycle, e-bike, or scooter accident: a randomized controlled trial

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

ABR	General Assessment and Registration form (ABR form), the application form that is required for submission to the accredited Ethics Committee; in Dutch: Algemeen Beoordelings- en Registratieformulier (ABR-formulier)
AE	Adverse Event
ATV	All-Terrain Vehicle
AR	Adverse Reaction
CA	Competent Authority
CCMO	Central Committee on Research Involving Human Subjects; in Dutch: Centrale Commissie Mensgebonden Onderzoek
CV	Curriculum Vitae
DC/TMD	Diagnostic Criteria for Tempero-Mandibular Disorders
DSMB	Data Safety Monitoring Board
E-bike	Electric bike
ED	Emergency Department
EU	European Union
EudraCT	European drug regulatory affairs Clinical Trials
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation; in Dutch: Algemene Verordening Gegevensbescherming (AVG)
HADS	Hospital Anxiety and Depression Scale
IB	Investigator's Brochure
IC	Informed Consent
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
ISS	Injury Severity Score
OHIP	Oral Health Impact Profile
METC	Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)
MMSE	Mini Mental State Examination
(S)AE	(Serious) Adverse Event
SPC	Summary of Product Characteristics; in Dutch: officiële productinformatie IB1-tekst
Sponsor	The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party

	that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.
SUSAR	**Suspected Unexpected Serious Adverse Reaction**
TBI	**Traumatic Brain Injury**
UAVG	**Dutch Act on Implementation of the General Data Protection Regulation; in Dutch: Uitvoeringswet AVG**
WMO	**Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen**

SUMMARY

Rationale: The use of electric bikes (e-bikes) and other motorized two-wheeled vehicles is growing substantially in the Netherlands. With that, the number of (elderly) patients presenting at the Emergency Department (ED) after a (electric) bicycle or scooter accident is growing along. This results in increased bicycle- and scooter related injuries. Patient information on the protective effects of helmets could be important in the prevention of bicycle and scooter related injuries and could lead to an increase of helmet use amongst (e-) cyclist. However, this is currently not part of standard management at the ED or in any other setting.

Objective: The *primary objective* is to investigate the difference of the proportion of helmet use between the two groups (intervention vs control group) amongst patients ≥60 years, six months after they have visited the emergency department after a bicycle or scooter accident.

Secondary objective;

The relationship between helmet use after 6 months and symptoms of anxiety and depression as measured with the Hospital Anxiety and Depression scale (HADS).

Study design: Randomized controlled trial.

Study population: Patients ≥60 years (non-helmet users), who visit the emergency department after a (e-) bicycle or scooter accident

Intervention (if applicable): Online educational video on helmet use.

Main study parameters/endpoints:

-Helmet use behaviour 6 months after attending the ED;

-Accident characteristics (location, weather conditions etc), injury characteristics (type of injury, location of injury, multiple injuries), and patient characteristics (education, age, intoxication etc).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All included patients need to fill out a short questionnaire at the ED, which takes less than 5 minutes. At the ED, patients are randomly assigned to the intervention group (educational video + regular healthcare) or control group (no video + regular healthcare). Watching the video itself will take less than 4 minutes. During the follow-up period, patients will be evaluated at 6 months by telephone interview. During this interview questions on helmet use will be asked, and this will take approximately 5 minutes. There are no invasive interventions and thereby the risk and burden associated with participation in this study is considered low.

1. INTRODUCTION AND RATIONALE

Bicycles and scooters are frequently used in the Netherlands and are, as well as in many other countries, an important way of transportation and a popular activity for recreation and leisure[1-3]. Next to bicycle and scooters, electric bikes (e-bikes) and (sharing) scooters have gained popularity over the past few years. For instance, the number of speed pedelecs (e-bikes that can reach speed levels of 45km/h) increased with 63% in the past 2 years.[4] With the increase in the use of e-bikes and (sharing) scooters, there is also an increase in e-bike and scooter related injuries. One out of five cyclist presenting to the ED after a bicycle accident was riding an e-bike.[5, 6]

Especially elderly have a higher risk for accidents, mostly because of their reduced eye sight and reduced judgement function (e.g. estimating distance, response to traffic changes). Due to arthralgia they experience more difficulty to get on and off the bike, and have limited rotation capacity with their neck for environmental awareness. Furthermore, they have a higher risk for injuries (e.g. due to osteoporosis, use of anticoagulants).[12] Data from 2019 show that in the Netherlands deadly (e-)bike accidents, were more often people aged ≥60 whereas people aged <59 were more often involved in deadly car- and motor accidents .[13] Same trends are seen in older adults in other countries such as Sweden.[14] That taken into account, older adults have become an interesting group for investigation as 65% of all e-bike owners in the Netherlands, are older than 65 years.[15]

Bicycle and scooter related injuries are mostly traumatic brain injury (TBI), fractures and soft tissue injuries.[16] Cranial and maxillofacial injuries are common as it takes up to 30 to 40% of total injuries.[3, 5, 10] The literature states that helmet use reduces TBI and craniofacial injuries after a bicycle or scooter accident.[3, 10, 17-20] Although conventional e-bikes can reach speed levels up to 25 km/h, wearing a helmet is not obligatory in the Netherlands for vehicles with a maximum speed of 25km/h (e bikes and scooters with a blue licence plate).[7] Except in bicycling sport, helmet use has not widely been accepted in the Netherlands, and as most cyclists do not see its significance[8, 9], helmets are only being used to a very small extent (1%) on a voluntary base.[5, 7, 10] A recent study in the United States, where helmet use is obligatory, found that only 4% of scooter users was actually wearing a helmet.[11]

Several studies have shown that promotion of bicycle helmets among children and young adults increases helmet use.[21-26] Rivara et al. reported that educating children and parents, and providing them with a helmet, increased helmet use from 5% to 40%.[24]. Ryan et al showed that an educational video for parents resulted in twice as much helmet use among their children [23] Furthermore, House et al. shows that video intervention at the ED changed parents' perception of all-terrain vehicle (ATV) safety for children significantly.[27] Also, instructions with an educational video at the ED appears to be an effective measure to educate patients after TBI, whereas patients were able to recall instructions more accurately after a few days.[28, 29] That being said, the effects of video instructions on helmet use behaviour in specifically adult cyclists and scooter users at the ED has not yet been investigated. Moreover, because education on helmet use is currently uncommon, and the use of helmets amongst adult cyclists remain limited in the Netherlands, it might be useful to provide video instructions on helmet use at the ED.

By conducting a randomized controlled trial, our primary aim is to investigate the effects of an educational video on future helmet use behaviour amongst adults above the age of 60 years, who visited the ED after a traffic accident with a (motorized) two wheeled vehicle.

2. OBJECTIVES

The *primary objective* is to investigate the difference of the proportion of helmet use between the two groups (intervention vs control group) amongst patients ≥60 years that have visited the emergency department after a (motorized) two wheeled vehicle traffic accident.

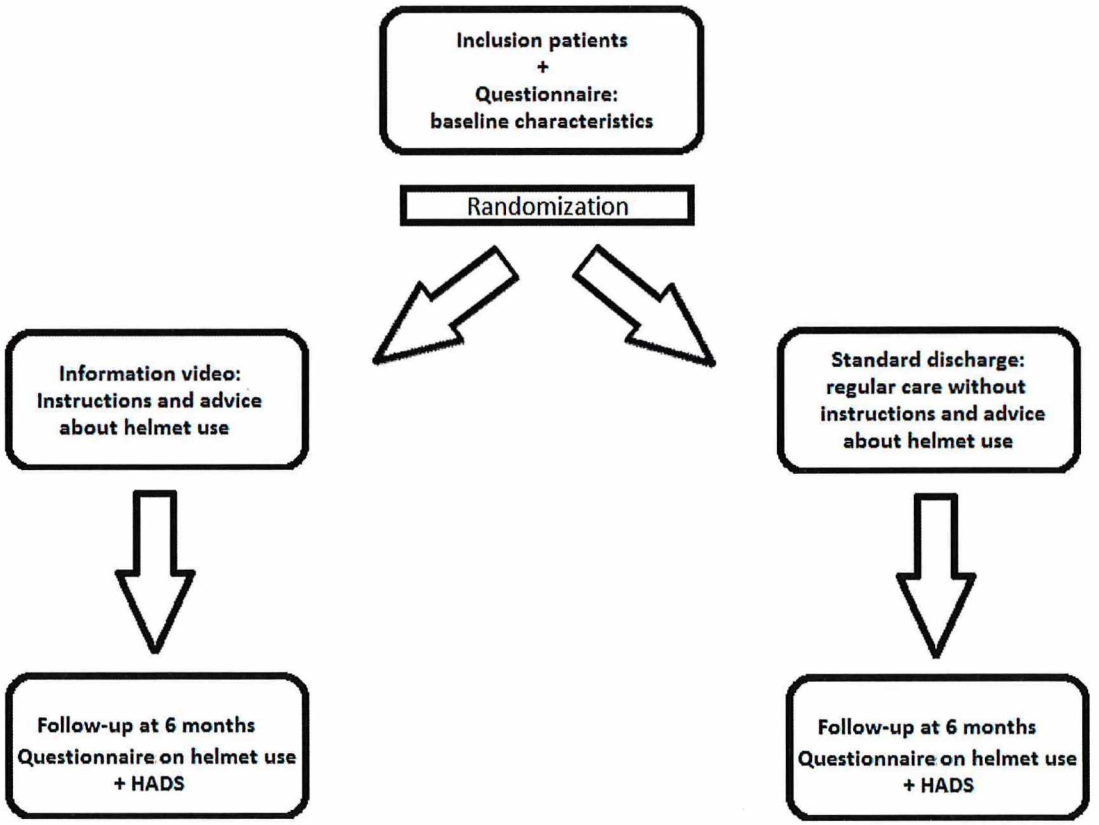
Secondary objective;
The relationship between helmet use after 6 months and symptoms of anxiety and depression as measured with HADS.

STUDY DESIGN

This study is a randomized controlled trial. After informed consent, eligible patients will be included at the ED. Observational data will be collected and patients need to fill out a short questionnaire to collect data regarding helmet use, vehicle, injury and accident circumstances.

Then, patients will be randomized into an intervention or control group. The intervention group will be shown an *educational video (max 4 minutes)* on helmet use next to standard care. The control group will only receive standard care, with no further information or education regarding helmet use. Patients will be approached by telephone after 6 months for follow up on helmet use behavior, which takes approximately 5 minutes.

Inclusion and randomization will be performed only when all the diagnostics at the ED are completed, and after informed consent.



STUDY POPULATION

2.1 Population: All patients ≥60 years (non-helmet users) presenting to the emergency department of the Erasmus MC, after a (electric) bicycle or scooter accident (all motorized two-wheeled vehicles including (light) mopeds, scooters with blue license plate (max 25km/h) and yellow licence plate (max 45km/h).

2.2 Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following inclusion criteria:

- Age ≥60 years
- Attending the ED after a (electric) bicycle or scooter traffic accident
- Signed informed consent by patient
- Maximum points (15) on Glasgow Coma Scale

2.3 Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Linguistic barrier
- Illiteracy or blindness
- Helmet use during the accident

2.4 Sample size calculation

Sample size calculations are based on previous studies on helmet use after education, which differ between 2% and 35% in prevalence. Based on those, we expect that the intervention will cause a 15% increase in helmet use. Therefore, the anticipated incidence of helmet use in the intervention group was estimated at 20%, and in the control group at 5% after 6 months. With an alpha of 0.05 and power set at 90%, the sample size is calculated at 220 (110 subjects per study group).

3. TREATMENT OF SUBJECTS

3.1 Investigational product/treatment

An online video with discharge instructions will be shown, and a link to the video will be provided in a leaflet.
In this video, which takes less than 4 minutes, information on helmet use and helmet protection will be given. Patients will be informed on the benefits of wearing a helmet during cycling in order to promote use in the future. The video will be watched at the emergency department under supervision of a healthcare provider, to ensure 100% compliance. These patients will receive a link where they can re-watch the video after medical discharge.

3.2 Use of co-intervention (if applicable)

Not applicable

3.3 Escape medication (if applicable)

Not applicable

4. INVESTIGATIONAL PRODUCT

Not applicable

5. NON-INVESTIGATIONAL PRODUCT

Not applicable

6. METHODS

6.1 Study parameters/endpoints

6.1.1 Main study parameter/endpoint

Helmet use in the two groups (intervention vs control group) 6 months after emergency department visit.

6.1.2 Secondary study parameters/endpoints

At baseline, at the ED

- Helmet use during accident
- Injury characteristics (type of injury, anatomical location of injury, neurological injuries, cervical spine injuries, mortality, injury severity score (ISS)[30])
- Specific circumstances (type of vehicle, speed of vehicle, type of accident (one-sided or two-sided, vehicles/subjects involved in the accidents), location of accident, weather, time and season, intoxication, type of helmet)

At follow up

- Questionnaire on helmet use at 6 months after ED visit (see questions paragraph 7.3)
-Hospital Anxiety and Depression Questionnaire (HADS)

6.1.3 Other parameters

Patient characteristics at baseline

- Age;
- Gender;
- Educational level/profession;
- Living situation;
- Intoxication;

6.2 Randomisation, blinding and treatment allocation

Patients will be randomized by computer by block randomization, stratified for gender. The intervention group will watch an educational video and receive standard care. The control group will only receive standard care. Due to the type of intervention, blinding for both patient and healthcare provider is not possible. The researcher, who will perform the telephone follow-up, will be blinded for the randomisation. However, to differentiate fully on behavioural change between the two groups, health care providers will be explicitly instructed to not provide verbal educational advice on helmet use at discharge.

6.3 Study procedures

Step1

After informed consent and inclusion in the study, patients will be asked to fill out a questionnaire provided by the physician at the ED. The questionnaire collects data on patient characteristics, as well as extra information on specific circumstantial factors (see study parameters 6.1.2.)

Step 2
Then patient will be randomized into the intervention group (educational video) or into the control group. The educational video is shown at he ED, before discharge.

Step 3
Follow-up at 6 months after ED visit to evaluate helmet use behaviour.

Table 1: questionnaires

Questionnaire	Outcome	Time	When
Patient and event characteristics*	Baseline information	5 min (1x)	After inclusion at the ED
Questionnaire on helmet use**	Helmet use	5 min (1x)	6 months follow-up
HADS questionnaire[31, 32]	Anxiety and depression symptoms	5 min (1x)	6 months follow-up
Total		**10 min**	

*** Questions regarding Patient and Event Characteristics at baseline**:
1A What type of vehicle were you driving?
1B At what speed where you driving when the accident happened?
1C Were you driving or were you a passenger?
1D What was the mechanism of injury? One sided fall or collision? Collision with another (moving) subject?
2A Were you intoxicated? With what?
2B What caused the trauma? Distraction / slippery road / vehicle malfunction?
3A How were the weather circumstances?
3B What was the location of the trauma?
4A What is your educational level and/or profession?
4B What is your living situation?

****Questions on helmet use after 6 months:**
1A Did you ever wear a helmet while using a bicycle, e-bike or a scooter before the accident?
1B Why did you (not) wear a helmet?
2A Are you wearing a helmet while using a bicycle, e-bike or a scooter now, 6 months after the accident?
2B Why are you (not) wearing a helmet now?
2C Do you think differently about helmet use after the ED visit?

3A Did your traffic behaviour change after your accident?
3B Did your bike/scooter/moped use change after the accident?
3C Are you recommending helmet use to others?
4A Should helmet use be obligatory?
4B If helmet use was obligatory, would you use it?
5A Do you still have physical complaints due to the accident?

6.4 Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

6.5 Replacement of individual subjects after withdrawal

No replacement will be included when a patients decides to withdrawal.

6.6 Follow-up of subjects withdrawn from treatment

No follow-up will be done when a patients decides to withdrawal.

6.7 Premature termination of the study

Not Applicable

SAFETY REPORTING

6.8 Temporary halt for reasons of subject safety

In accordance to section 10, subsection 4, of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise subject health or safety. The sponsor will notify the accredited METC without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the accredited METC. The investigator will take care that all subjects are kept informed.

6.9 AEs, SAEs and SUSARs

Not applicable

6.9.1 Adverse events (AEs)

6.9.2 Serious adverse events (SAEs)

6.9.3 Suspected unexpected serious adverse reactions (SUSARs)

6.10 Annual safety report

Not applicable

6.11 Follow-up of adverse events

Not applicable

6.12 [Data Safety Monitoring Board (DSMB) / Safety Committee]

Not applicable

7. STATISTICAL ANALYSIS

Statistical analysis was performed in IBM Statistical Package for Social Sciences version 25 or higher. A p-value <0.05 will be considered significant.

7.1 Primary study parameter(s)

The difference in proportion of helmet use 6 months after visiting the emergency department will be analysed using the Chi-square test in SPSS 25. Patients with unknown helmet use will be excluded from the analysis of the primary study outcome.

7.2 Secondary study parameter(s)

The Spearman's rank correlation coefficient will be used to determine the association between helmet use and the subscores for anxiety and depression on the HADS questionaire. We will use linear regression analyses to determine the association between socio-demographics, helmet use, and HADS subscores. Overall p-values <0.05 were considered to indicate statistical significance

7.3 Other study parameters

7.4 Interim analysis (if applicable)

Not applicable

8. ETHICAL CONSIDERATIONS

8.1 Regulation statement

This study will be conducted according to the principles of the Declaration of Helsinki (October 2013) and in accordance with the Medical Research Involving Human Subjects Act (WMO).

8.2 Recruitment and consent

Patients visiting the ED after a (e)bike or scooter accident, and meet the inclusion criteria, will be asked for informed consent. The attending physician will inform the patient about the study and give the Patient Information Form (PIF). Patient should decide if they are willing to give consent before leaving the ED, and will at least have 30 minutes to consider their decision.

8.3 Objection by minors or incapacitated subjects (if applicable)

Not applicable.

8.4 Benefits and risks assessment, group relatedness

There are no expected negative effects from participating in the study. It takes less than 4 minutes to watch the video. It takes 5 minutes to fill-out questionnaires at the ED. Patients do not need to come to the hospital specifically for follow up on helmet use behaviour. The telephone follow up interview will take around 5 minutes.

8.5 Compensation for injury

Not applicable

8.6 Incentives (if applicable)

Not applicable

9. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

9.1 Handling and storage of data and documents

Patient data will be coded by a study serial number. In this way the data will be pseudo-anonymised and untraceable to individual patients. The coordinating investigator and principal investigator are the only ones who will have access to the source data. Informed consent and patient ID will be stored separately from the study data. Data will be kept for 15 years after the study is completed. All data will be handled with care. The handling of data will comply with the EU General Data Protection Regulation and the Dutch Act of Implementation of the General Data Protection Regulation (in Dutch: Uitvoeringswet AVG, UAVG).

9.2 Monitoring and Quality Assurance

Not applicable

9.3 Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be notified to the METC that gave a favourable opinion.

9.4 Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

9.5 Temporary halt and (prematurely) end of study report

The investigator/sponsor will notify the accredited METC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient's last visit.

The sponsor will notify the METC immediately of a temporary halt of the study, including the reason of such an action.

In case the study is ended prematurely, the sponsor will notify the accredited METC within 15 days, including the reasons for the premature termination.

Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited METC.

9.6 Public disclosure and publication policy

Results will be published in a peer-reviewed journal.

10. STRUCTURED RISK ANALYSIS

Not applicable

10.1 Potential issues of concern

10.2 Synthesis

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