Fitness to drive in older persons with cognitive impairments

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39431

Source
ToetsingOnline

Brief title
FitCI

Condition

- Structural brain disorders
- Dementia and amnestic conditions

Synonym
cognitive impairment, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,CBR, Rijswijk,Ministerie van Infrastructuur en Milieu ,Schuhfried GMBH, Hyrtlstrasse 45, 2340 Mödling, Österreich,Stichting Wetenschappelijk Onderzoek Verkeersveiligheid (SWOV),

Leidschendam,STsoftware, Vredelust 9, 9723 ZD Groningen, The Netherlands

Intervention

Keyword: dementia, driving simulator, fitness to drive, neuropsychological tests

Outcome measures

Primary outcome

Nosological dementia diagnosis (dementia of Alzheimertype, Frontotemporal dementia, Lewybody dementia, Parkinson's disease dementia)

Severity and cognitive profile of the the disorder

Level of education and driving experience

Performance on neuropsychological tests

Performance on testdrive in driving simulator (objective measures like time to collision and lateral position on the road)

Performance on on-road testdrive (subjective evaluations given by examinator: yes/no judgment and a more detailed form (TRIP))

Secondary outcome

not applicable

Study description

Background summary

In our aging society, the segment of elderly with functional disorders will grow in the population of road users. Being able to drive is very important for the independence and wellbeing of elderly. However, disorders and illness can affect the fitness to drive negatively. Especially for cognitive disorders like dementia it is unclear when to draw the line and how the fitness to drive can be determined. The *Regeling eisen geschiktheid 2000* from the Dutch Ministry of Infrastructure and Environment contains the Dutch regulations about these criteria. However, at the moment the formal criteria are merely described,

without specifying the assessment methods.

Study objective

The most important objective of this study is the validation of various examination procedure to assess fitness to drive in older persons with cognitive impairments. The assessment procedure comprises nosological dementia diagnoses (e.g. AD, FTD) , profile and severity of the cognitive impairments (CDR) , biographical data and driving experience, dedicated neuropsychological and visual tests and test-drives in a driving simulator and on-road. We will investigate the mutual relations between these various domains . An essential part of the study is the on-road test of the CBR (practical fitness to drive) which is the Dutch 'golden standard' for determining fitness to drive in the case of cognitive impairment.
For the neuropsychological tests and the simulator driving test, normative data will be collected and we will form and test models to predict practical fitness to drive from combinations of data in the various domains.
Specifically, we expect that the relationship between neuropsychological test results and practical fitness to drive depends on the nosological dementia diagnosis and the profile of dementia.
Based on the knowledge we will gather during the study, we will improve tje procedure of testing the fitness to drive of people with mild or very mild dementia. This will result in less burden and costs for the patients and organizations involved.

Study design

All participants will follow the same procedure:
Fill out a questionnaire (about the driving behavior of the participant)
Interviews of patients and partners (CDR and MMSE, driving experience,education)
Neuropsychological examination (neuropsychological tests of visual, visual-motor and cognitive functions important for driving)
Driving simulator (to provide performance based measures of practical fitness to drive)
On-road driving test (the Dutch golden standard, a subjective evaluation of practical fitness to drive)
Feedback on the results and advice
Follow up via phone

Study burden and risks

The participants will be attending the researchcenter once for the NPO and the tests in the driving simulator. This takes about 3,5 hours to complete. Breaks will be added if necessary. On a seperate day, an appointment will be made with the CBR for the on road driving test. The on road driving test takes one

hour of the participants time. Participants will receive feedback on the results and an advice based on these results. After 3 to 4 months, they will receive a phonecall from the researcher with questions about whether they ceased driving and there general health.

Persons with MCI or (very) mild dementia (CDR 0.5 en CDR 1) will generally be asked to participate shortly after having received the diagnosis.
Participation has the advantage of having a comprehensive driving evaluation without direct consequences for their driving license, including an on road test by the CBR. However, the results of the on-road test can labeled as official if a subject asks for it. This could occur in case he/she performed adequately on the on-road test; in that case the license will be renewed for 1-3 years. In case the subject failed the on-road test, he or she will, depending on the performance, be advised to take driving lessons and have an official examination afterwards, or to stop driving and handing in the license. This advice will not be reported to the CBR however.
Besides, persons with CDR=0.5 and a positive result in the on-road test, have the advantage that the neuropsychological assessment which is essential for an extension of the driving license longer than a year is without costs for them. In all cases the results of the examination will be discussed with the subjects and families.

While driving the driving simulator it is possible that the participant will get 'simulator sickness'. We will inform the participant beforehand that this is possible. During the driving simulator tests, the physical wellbeing of the participants is being monitored carefully. If the participant is not feeling well, the simulator is stopped immediately. The driving simulator-part of the study will be terminated for this participant. When the participant is feeling well enough to go home, he/she is allowed to do so.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Older than 50 years
Very mild or mild dementia (clinical dementia rating(CDR) 0,5 and 1)
Has a valid driving license, or had a valid driving license until recently
Has the intention to keep driving

Exclusion criteria

Stroke
Visual acuity <= 0.5
Other serious disorders with consequences for fitness to drive

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2013
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	29-01-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-02-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-06-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL39622.042.12