Fitness-to-Drive and Risk acceptance in Huntington's disease

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational non invasive

Summary

ID

NL-OMON54606

Source
ToetsingOnline

Brief title
FTDr in HD

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Movement disorders (incl parkinsonism)

Synonym
Huntington's disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: FTDr, Huntington, Simulator, Social cognition

Outcome measures

Primary outcome

Development of cognitive profiles to assess FTDr in HD patients determined by an regression analysis.

For each variable z-scores will be calculated. These z-scores will then be combined into four categories:

1. Cognitive speed and attention including the following test variables: Rey complex figure, TMT-A, Stroop I-III, SDMT, Category fluency, ATAVT, and RT S1-S2.

2. Executive functions, including the following test variables: TMT-B, Letter fluency, and SWOV.

3. Social cognitive functions, including the following test variables: FEEST and IGT.

4. Procedural driving skills, including the following test variables: Swingdrives fixed and free, Intersections, and Merging.

With these categories we will perform a regression analysis to determine the predictive value of each category for FTDr in HD.

Secondary outcome

Other questions that will be addressed during the course of the study are:

• Is there a relationship between levels of self-awareness, as measured by tests that call upon self-awareness (i.e. the SWOV, WRBTV, and Swingdrive), and

the result of the on-road driving test?

• What is the relationship between UHDRS motor score and FTDr?

Study description

Background summary

Huntington*s disease (HD) is an autosomal dominant neurodegenerative disorder which is characterised by a triad of symptoms: motor, cognitive and behavioural. These symptoms in HD eventually lead to significant decline in (instrumental) activities of daily living ((i)ADL). The cognitive, motor, and visual functions that are required for adequate procedural driving skills in a motor vehicle show a progressive decline in HD as well. Patients with HD are at a greater risk of overestimating their driving skills and fitness-to-drive (FTDr) because of impaired self-awareness, which may already be present in presymptomatic gene carriers. Overestimating FTDr could lead to potential dangerous situations for HD patients* self and others.

With the proposed study we plan to establish cognitive profiles with classic neuropsychological tests that correlate with FTDr in HD patients; 1) Fit to drive, 2) No longer fit to drive, and 3) Dubious fit to drive. For HD patients who fall into the dubious category, additional testing is required to provide a more decisive answer regarding their FTDr. In these situations a driving simulator test, to assess procedural driving skills, in conjunction with the cognitive profile could clarify the remaining ambiguities. When we are able to correctly identify patients* FTDr on base of classic neuropsychological tests and driving simulators assessments, on-road driving tests can be implemented more specific. This in turn, makes FTDr assessment more cost-effective, safer and expeditious.

Study objective

We aim to develop three cognitive profiles to assess FTDr in HD patients; 1) Fit to drive, 2) No longer fit to drive, and 3) Dubious fit to drive and no longer fit to drive. The profiles will be determined with classic neuropsychological tests, complemented with tests that focus specifically on FTDr, and driving simulator tests.

Study design

We propose a cohort study of a population of HD patients.

Study burden and risks

All participants will attend one test session at the University Medical Center Groningen (UMCG) for the neuropsychological assessments and the driving simulator tests. The duration of this session is approximately 4 hours, excluding intermissions (which are set at the participants* request). The on-road driving test will be scheduled on a later date at the participant*s local office of the Dutch driver licensing association; Centraal Bureau Rijvaardigheidsbewijzen (CBR). The driving test has a maximum duration of 60 minutes. Participants will receive feedback of their performance on the driving test by the examiner of the CBR.

Benefits of participation in the study are a free extensive assessment of driving ability. A fail on the driving test has no immediate consequences for the participant*s drivers* license. Participants who have failed the driving test are advised to cease driving. However, this advice is not binding. Participants may experience simulator sickness (similar to car sickness) during the driving simulator test. Participants are notified of this possibility beforehand and they will be monitored during the test. They will also be informed of their right to stop the test at any time.

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

Confirmed diagnosis of Huntington*s Disease via CAG-repeat length analysis
Between 18 and 74 years of age.
Dutch speaking.
Hold a drivers* licence.

Exclusion criteria

Individuals who do not meet the inclusion criteria

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2016
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	13-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-01-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-04-2023
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	NL53660.042.15