YOD-RiSoCo: Social Cognition and Risk-taking Behaviour in Patients with Young-onset Dementia

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Ethical review	Approved WMO
Status	Pending
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON57207

Source
ToetsingOnline

Brief title
YOD-RiSoCo

Condition

- Neurological disorders NEC

Synonym
Alzheimer's dementia, Frontotemporal dementia, Young-onset dementia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Risk-taking behaviour, Social Cognition, Young-onset Dementia

Outcome measures

Primary outcome

The overarching aim of this study is to develop sensitive measures for aspects of social cognition that are crucial for the abilities to display adequate social-interpersonal behaviours, including traffic safety, as well as to develop better assessment procedures for unsafe, risk-taking behaviour endangering other people. These measures will result in better measurement of impairments in social cognition and behaviour, which will attribute to better detection of SC problems in all (frontal) brain injury patients, and a more timely diagnosis of these behavioural YOD subtypes. This will be done by comparing patients with behavioural variants of YOD and frontal brain injury to patients with non-behavioural variants of YOD and non-frontal brain-injury, and to healthy controls on measures of social cognition and risk-taking behaviour. This way, we can see if the newly developed measures are sensitive for frontal brain pathology.

Secondary outcome

Subsequently, we will investigate validity of the new measurements by relating it to other social cognitive and other cognitive measures. We will also assess whether and how impairments in aspects of social cognition are related to risk-taking behaviour to determine if the SC test are able to predict risk-taking behaviour. Furthermore, the aim is to develop driving simulator scenarios eliciting risk-taking behaviour in patients that can possibly be of

use in the judgement of fitness to drive of patients with YOD, but also in other patient groups in which behavioural problems occur frequently, such as patients with frontal brain injury. As a result of this study, we hope to aid to the diagnosis of social behavioural symptoms and a timely identification of unsafe risk-taking behaviour, in particular in traffic, in patients with YOD and other neurological conditions affecting frontal functions.

Study description

Background summary

Young-onset Dementia (YOD) refers to dementia with the onset before the age of 65 years. A common type of YOD is frontotemporal dementia (FTD), but there can also be young onset types of Alzheimer*s disease, as well as many other different subtypes. Characteristic of YOD is that impairments in language, perception or (social) behavioural changes are more prominent in the early disease stages than memory impairments. These symptoms are often under-recognized, which delays the diagnosis of YOD and consequently contributes to a much more difficult situation for both patients and their close others. An important affected domain in various subtypes of YOD, is social cognition (SC). SC refers to the capacities that enable adequate social behaviours and interactions and includes aspects such recognition of other person*s emotional expressions, the ability to experience emotions, empathy and perspective-taking or theory of mind (ToM). SC is underpinned by frontal-subcortical networks, which are affected in specific subtypes of YOD.
In addition, impairments in social cognition are also frequent symptoms in patients with neurological disorders which affect frontal-subcortical networks, such as severe traumatic brain injury (TBI) or frontally located brain tumours. Impairments in SC involve an inability to detect emotional signals that indicate danger during decision-making, or to take other people*s feelings and perspective into account. Hence, such impairments are frequently linked to inadequate, inappropriate or even problematic social behaviour, so called *behaviours of concern, which are potentially harmful to other people such as aggression or unsafe driving.
At present there are only a few neuropsychological tests available that measure aspects of SC, but to date, tests that reliably measure the abilities to have empathy with others and to take their perspective, and to feel emotions and take these into account in situations involving the safety of other people are still lacking. Hence, there is a large unmet need for better neuropsychological

measures of social cognition that are sensitive to impairments in social cognition, also allowing a more timely diagnosis of the specific subtypes of YOD. Moreover, there is also a lack of assessment procedures that can reliably identify patients that have a high risk to display unsafe behaviours, in particular in traffic situations. An additional problem is that to determine whether patients with early dementia are still safe to drive, the measure that is used (the CDR score) relies heavily on the presence of memory problems. Hence, YOD patients with intact memory but severe SC impairments might still be considered fit to drive.

Study objective

The overarching aim of this study is to develop sensitive measures for aspects of social cognition that are crucial for the abilities to display adequate social-interpersonal behaviours, including traffic safety, as well as to develop better assessment procedures for unsafe, risk-taking behaviour endangering other people. These measures will result in better measurement of impairments in social cognition and behaviour, which will attribute to a more timely diagnosis of these behavioural YOD subtypes. Also, if we can establish that the new tests for social cognition significantly relate to the measurements of unsafe driving behaviour, these tests can also be used for timely identification of patients at risk for displaying these unsafe behaviours. And finally, having better assessment procedures for unsafe driving behaviours will aid in deciding whether patients with early YOD but no memory deficits and other neurological conditions affecting frontal functions are still fit to drive. We will develop sensitive measures for different aspects of social cognition (empathy, theory of mind, emotion experience) and for risk-taking behaviour.

Study design

This study is designed as an observational and experimental case-control study.

Study burden and risks

There are no direct benefits for the patient. A potential risk is simulator sickness (similar to car sickness) during the driving simulator test. Participants are notified of this possibility beforehand and will be monitored during the test. They will also be informed of their right to stop the test at any time. A general risk is that assessments (neuropsychological assessment and driving simulator assessment) can be too demanding for patients; however, neuropsychologists carrying out the assessments are experienced in testing vulnerable patients and will carefully monitor whether the assessments are too demanding, and quit if necessary.

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

All subjects
- Sufficient command of the Dutch language
- Any driving experience throughout life
- Age 18 to 70

bvYOD subjects
- Probable diagnosis of young-onset (before 65 years old) bvFTD according to the current criteria (Rascovsky et al., 2011) or bvAD according to criteria current criteria (McKhann et al., 2011), or another behavioural YOD subtype, confirmed after interdisciplinary consensus meeting in which interviews, neuropsychological examination, neurological and psychiatric assessments, neuro-imaging, blood samples, and in some cases FDG/PIB-PETscans, CSF

biomarkers or genetic counselling were discussed.

Non-bvYOD subjects
- Probable diagnosis of young-onset dementia (before 65 years old) other than a behavioural YOD subtype such as bvFTD or bvAD, for example amnestic variant AD, confirmed after interdisciplinary consensus meeting in which interviews, neuropsychological examination, neurological and psychiatric assessments, neuro-imaging, blood samples, and in some cases FDG/PIB-PETscans, CSF biomarkers or genetic counselling were discussed.

Frontal brain injury subjects
- Patients with frontal brain injury (e.g. traumatic brain injury, stroke or brain tumour patients).
Non-frontal brain injury subjects
- Patients with non-frontal brain injury (e.g. traumatic brain injury, stroke or brain tumour patients).

Exclusion criteria

YOD subjects:
- Presence of premorbid severe neurological or psychiatric pathology, non-related to dementia.

Brain injury subjects:
- Presence of serious psychiatric disorders or other neurological comorbidities.

Healthy control subjects:
- Presence of serious psychiatric disorders
- History of neurological disorders, which may interfere with cognitive functioning (e.g. recent concussion, previous subarachnoid or intracerebral haemorrhage, intracranial tumours, epilepsy, ischemic stroke).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	156
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-12-2024
Application type:	First submission
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
ClinicalTrials.gov	NCT06286293
CCMO	NL87304.042.24