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

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

Summary

ID

NL-OMON57234

Source
ToetsingOnline

Brief title
YOD-RiSoCo

Condition

- Neurological disorders NEC

Synonym
Alzheimer's dementia, Frontotemporal dementie, 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 main study parameter is sensitivity of the new SC tests, assessed by SC performance of patients with bvYOD compared to healthy controls. Subsequently, we will investigate construct validity of the new measurements by relating it to other social cognitive and other cognitive measures.

Secondary outcome

In a subset of the participants assessed for the main study parameters, complemented by a group of non behavioural YOD and frontal brain injury patients, the ecological validity of the new SC tests will be exploratorily investigated by assessing the relationship between the SC tests and measures of risk-taking behaviour.

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 subtypes 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 usually more prominent in the early disease stages than memory impairments, which are the hallmark of late onset dementia, in particular Alzheimer*s disease. These non-memory 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 particular in frontotemporal dementia and behavioural variant of Alzheimer*s disease. Similar, impairments in social cognition are also found in patients with other neurological disorders that mainly affect frontal-subcortical networks, such as severe traumatic brain injury (TBI) or frontally located brain tumours.
A major characteristic of impaired SC is emotional flattening. Patients experience no or less (bodily feelings of) emotions. Being able to feel one*s own emotions is a prerequisite for emotional empathy, since the ability to empathize with others involves sharing feelings. Such an inability to detect emotional signals, for instance feelings of fear, that indicate danger during decision-making, or to take other people*s feelings and perspective into account is likely to result in 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. Even more so, tests that reliably measure the abilities to feel emotions, to have empathy with others and to take others* emotions and perspective 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 these impairments in emotional feelings and empathy (indicating possible risk of behaviours of concern). Having such measures available will also likely allow a more timely diagnosis of the specific behavioural subtypes of YOD.

Study objective

The overarching aim of this study is to develop new, sensitive measures for aspects of social cognition (emotion experience, empathy and affective theory of mind), that will contribute to a better and earlier diagnosis of specific subtypes (the behavioural variants, bv) of YOD. To this end, the first step is to assess the sensitivity of the newly developed measures for these aspects of social cognition, by comparing the performance of patients with a bvYOD diagnosis to the performance of healthy controls. In addition, construct validity will be investigated by relating performance on the new SC tests to existing social cognitive tests (convergent validity) and other general, non-social cognitive tests measuring for example memory, information processing speed and attention (divergent validity).
In a second, smaller sub-study, it will be explored whether the new tests are also ecologically valid, that is, are related to unsafe, risk-taking behaviour in real life situations. To this end, we will make use of driving simulator scenarios created to elicit risk-taking behaviour, and to simulate a real world environment, without the unwanted possibility of eliciting risk-taking dangerous behaviours in real world situations. The aim of this sub-study is to investigate whether impaired performance on the new SC tests is related to

risk-taking behaviour. First, this will be analysed in patients already diagnosed with bvYOD, but also in other patients with frontal damage, to investigate whether this relation is generic (with the future purpose that the tests may be broader applicable in the future than only for the diagnosis of YOD). Second, to investigate whether this relationship is specific, patients with non-bvYOD variants will be included in the analyses, for whom no SC impairments or risk-taking behaviour are expected.

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

Main study

All subjects
- Sufficient command of the Dutch language
- 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.

Additional criteria for additional Risk-taking assessment

All subjects
- Any recent (<5 years) driving experience

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:	Recruiting
Start date (anticipated):	25-02-2025
Enrollment:	168
Type:	Actual

Medical products/devices used

Registration:	No

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	NL87574.042.24