Social cognition and language in patients with gliomas: putting feelings into words?

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The main research objective is to examine the influence of language impairments on social cognition (emotion recognition, Theory of Mind (ToM) and affective empathy), in patients with (suspected) gliomas. Secondary objectives are 1) to determine if...

Ethical review	Approved WMO
Status	Pending
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON53289

Source
ToetsingOnline

Brief title
Social cognition and language in patients with gliomas

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, glioma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,BCN (Research School of Behavioural and Cognitive Neurosciences) Seed Grant

Intervention

Keyword: glioma, language, social cognition

Outcome measures

Primary outcome

The main study parameters are outcomes on measures for social cognition and language.

Social cognition measures:

- The Ekman 60 faces test of the Facial Expressions of Emotion Stimuli and Tests (emotion recognition)

- Cartoons test (ToM)

- Faux Past test (ToM, affective empathy).

Measures for language:

- letter and category fluency (verbal fluency, executive control)

- shortened version of the Boston Naming Test (visual confrontation naming)

- ScreeLing (screening of linguistic deficits)

- subtest of the Semantische Afasie Nederland (SAN) test (language comprehension).

Secondary outcome

Patients

To assess spontaneous and general language, the following measurements will be used:

* The Cookie Theft Picture Test

* Story telling (Fairy Tale and Christmas story)

* QuEST-NL

Patients and proxies

Three questionnaires will be used to examine social abilities and interaction:

* Interpersonal Reactivity Index (IRI) - empathy

* Dysexecutive Questionnaire (DEX) - difficulties in everyday situations

* Couples Satisfaction Index (CSI) - relationship satisfaction

Other study parameters:

Demographic data (including age, gender and education level) and information regarding tumor characteristics (classification of tumor type, tumor location, molecular mutations) will be obtained from the patient's medical reports.

Furthermore, general cognitive abilities will be measureds using the following tests, allowing to control for severe cognitive impairment that may interfere with the performance on tests for social cognition and language.

* Rivermead Behavioral Memory Test (RBMT) - verbal memory

* Rule Shift Cards Test - cognitive flexibility

Study description

Background summary

Patients with gliomas often suffer from lower quality of life, and detrimental social interactions after diagnosis. Two cognitive processes are crucial for

maintaining healthy social relationships and interacting with others: social cognition and language. Social cognition is the ability to recognize and process mental and emotional states and to react appropriately in social situations. Social cognition and language are separate cognitive functions that can be affected in different ways in patients with brain injury. Also, distinct cognitive measurement instruments are used to assess both processes. However, there appears to be a certain overlap between social cognition and language. Reacting adequately in social situations requires both verbal and non-verbal communication and to communicate feelings, thoughts and intentions, people often use language. That is, verbal communication is part of a symbolic system that makes social interaction possible. Therefore, language abilities seem to be important to social cognition.

Research shows that language is frequently impaired in adult patients with gliomas. Importantly, recent evidence suggests that social cognition can also be impaired in this patient group. However, no studies have been conducted into the influence of language on social cognition in patients with gliomas. Increasing knowledge on the influence of language difficulties on social cognition, will improve diagnostic accuracy. Eventually, this will lead to better, tailor-made treatments for these problems that negatively affect daily functioning.

Study objective

The main research objective is to examine the influence of language impairments on social cognition (emotion recognition, Theory of Mind (ToM) and affective empathy), in patients with (suspected) gliomas.

Secondary objectives are
1) to determine if patients with gliomas show impairments in different aspects of social cognition, i.e. emotion recognition, ToM, empathy and self-awareness;
2) to assess specific language impairments by looking at item-level characteristics of language tasks (e.g., analyses of word properties of fluency tasks, errors during object naming or spontaneous speech);
3) to determine which tumor characteristics (low- or high-grade, genetic mutation, tumor location and volume) are associated with different aspects of language and social cognition.

Study design

Cross-sectional study, data collected 1 to 3 weeks pre-operatively.

Study burden and risks

The proposed study is an observational study with no known health risks. At present, a neuropsychological assessment (NPA) is already part of routine

clinical care for all patients with low-grade gliomas referred for surgery. For these patients, a few tests (2 for social cognition and 3 for language) will be added to this routine clinical NPA. Thus: only for the patients with high-grade gliomas referred for surgery, the proposed tests will be an addition to routine clinical care. The NPA will take a maximum of three hours. The NPA can potentially be tiring for patients. However, patients will be able to take breaks in between and an experienced neuropsychologist will supervise the NPA, thus patients* energetic status and well-being will be carefully monitored. The neuropsychologists on the department of Neurology/Neurosurgery, unit Neuropsychology, have ample experience regarding NPA in patients with gliomas. Overall, it can be concluded that the majority of patients are able to undergo a NPA of maximum 3 hours, without adverse consequences. There are no direct benefits for the individual patient from participation. Increasing knowledge on the overlap between both functions and the relationship with certain tumor characteristics, will improve diagnostic accuracy and eventually lead to better, tailor-made treatments for language and behavioral problems that negatively affect daily functioning.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient with suspected glioma, i.e. low- or high-grade gliomas.
- Age older than 18 years
- Sufficient command of the Dutch language
- Being able to understand the instructions of the neuropscyhological assessment and to mentally and physically sustain/endure the assessment; this will be assessed in a consultation between treating physician (neurosurgeon) and investigator (neuropsychologist).

Exclusion criteria

- Serious neurodegenerative or psychiatric conditions (including addiction)
- Serious (other) medical conditions or physical inability hindering patients to come to the hospital
- Patients who need to undergo emergency craniotomy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2023
Enrollment:	60

Type:	Anticipated

Ethics review

Approved WMO Date:	28-06-2023
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	NCT05764460
CCMO	NL83778.042.23