

Social cognition in brain tumor patients

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This study aims at determining to what extent brain tumor patients have limitations in social cognition, if these limitations are dependent on patient, tumor, or treatment characteristics, and how these limitations affect functioning of informal...

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

Summary

ID

NL-OMON43201

Source

ToetsingOnline

Brief title

Social cognition in glioma

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym

glioma, primary brain tumor

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: glioma, social cognition, treatment, tumor location

Outcome measures

Primary outcome

The extent to which social cognition, and more in specific, perception of emotions, is affected in brain tumor patients.

Secondary outcome

Investigate possible determinants of compromised social cognition, including cognitive functioning, tumor location, tumor grading, and interventions.

Determine the association between social cognition of the patients and mental health of informal caregivers.

Study description

Background summary

Gliomas are the most common primary malignant brain tumors, with an incidence of about six per 100,000. Despite efforts in improving the treatment of gliomas, these tumors cannot be cured. Besides physical complaints, and complaints of fatigue and depression, 80% of primary brain tumor patients have cognitive deficits. Patients with inadequate awareness of these deficits may adopt maladaptive responses to their social environment. A lack of self-awareness can furthermore lead to perspective-taking difficulties that are associated with impaired social cognition, which entails emotional processes (perception of emotions, emotional empathy), and rational processes (*theory of mind*, cognitive empathy, pragmatic inference). Nevertheless, self-awareness has hardly been studied in brain tumor patients. For partners, these changes in behavior and personality are often described as the most problematic consequences of the disease, and the emotional distress in partners increases as patients are less aware of these consequences. Considering the significant overlap in the brain regions that are affected by brain tumors and/or their treatment and the brain regions that are essential for social cognition, social cognition is likely to be affected in these patients.

Study objective

This study aims at determining to what extent brain tumor patients have

limitations in social cognition, if these limitations are dependent on patient, tumor, or treatment characteristics, and how these limitations affect functioning of informal caregivers. Identification of brain regions involved in social cognition can be used for optimizing safe brain tumor surgery and be integrated in rehabilitation for patients with gliomas and their informal caregivers.

Study design

The study will be designed as a cross-sectional study.

Study burden and risks

Assessment of functions and consequent failure on these assessments can be confronting. Participants may always choose not to answer questions or perform assessments that they are uncomfortable with. Furthermore there are no risks but also no direct benefits for patients and their informal caregivers.

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

In order to be eligible to participate in this study, patients must meet the following criteria:

- 1) Histological diagnosis of glioma, being astrocytoma, oligodendroglioma, oligoastrocytoma, or glioblastoma multiforme
 - 2) Patients are not under active treatment with radiotherapy and/or chemotherapy
 - 3) ≥ 18 years of age
 - 4) Written informed consent
- In order to be eligible to participate in this study, informal caregivers must meet the following criteria:
- 1) ≥ 18 years of age
 - 2) Written informed consent

Exclusion criteria

- 1) Insufficient mastery of the Dutch language
- 2) Currently under active treatment for psychiatric disorders
- 3) Autism Spectrum Disorder or recurrent psychoses
- 4) Self-reported substance abuse
- 5) Major head trauma not related to the brain tumor or treatment
- 6) Neurodegenerative disorders
- 7) Severe visual impairments

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:	Basic science

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 20-02-2017
Enrollment: 300
Type: Actual

Ethics review

Approved WMO
Date: 22-12-2016
Application type: First submission
Review commission: METC Amsterdam UMC

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	NL57198.029.16