# Verb processing and verb learning in children with paediatric posterior fossa tumours

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Miscellaneous and site unspecified neoplasms benign |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON56817

**Source**
ToetsingOnline

**Brief title**
VePLIC-PFTs

### Condition

- Miscellaneous and site unspecified neoplasms benign
- Head and neck therapeutic procedures

**Synonym**
brain tumors, cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Rijksuniversiteit Groningen
**Source(s) of monetary or material Support:** NWO

## Intervention

**Keyword:** Brain, Children, Tumor, Verb processing

## Outcome measures

### Primary outcome

For the behavioural data, the main study parameters are the scores on each of the language tests administered (e.g., sum of words/sentences correctly recalled/named/understood for each child). For MRI, the main parameters are white matter integrity and microstructure and grey matter thickness, volume and area.

### Secondary outcome

N.A.

# Study description

### Background summary

Survivors of paediatric posterior fossa tumours (PPFTs) often present with cognitive impairments, and are less likely to finish high school than healthy peers. Importantly, the amount of words they know (their vocabulary) is related to their school achievements. Nonetheless, current research typically describes vocabulary size, while a deeper understanding of language (i.e. lexical-semantic processing, word learning abilities, and impairments in learning mechanisms) is crucial for selecting appropriate intervention strategies.

### Study objective

As verbs are better indicators of everyday language ability than nouns, the current project characterizes verb processing and verb learning abilities of children with PPFTs, and compares them to the abilities of typically developing children (aim 1). In addition, neural correlates of language abilities will be studied (aim 2), while studying the effects of treatment (surgery, chemotherapy, and proton therapy) on language ability, as well as the relationship between changes in language and neuroanatomical changes during and

after the proton therapy treatment (aim 3).

**Study design**

This is an observational study. Children with PPFTs will be tested during the course of their post-surgical treatment, approximately at 0-2 months, 12 months, and 24 months after surgery. All aspects of the medical treatment follow standard clinical protocols, without any manipulation related to participation in the research. It is, therefore, not an intervention study. However, in the context of this research, children will complete language and other cognitive assessment tasks at each assessment moment, and the assessment moments are chosen strategically to observe cognitive and neuroanatomical changes associated with different moments of the treatment pathway. Regarding the first timepoint: Given the standard clinical protocols for the different etiological groups, the post-surgical scan is gathered sometime between 2 weeks after surgery and not later than 1 week into the RT (normally up to 6 weeks). The language tests will be administered as early as possible within this interval.

Additional MRI data will be gathered in UMCG 12 months after surgery. In addition, routinely gathered neuroimaging data (MRI) and part of the neuropsychological assessment data collected during the standard clinical assessments will be shared with the researchers, through data sharing agreements. A sample of typically developing children, made primarily of siblings, will also be recruited and act as the control sample. Controls will be matched in age, gender, and parental education, and will be retested at the same intervals as patients, in order to support both cross-sectional (for aims 1 and 2) and longitudinal comparisons (for aim 3).

Verb processing and learning ability will be studied in the context of various levels of syntactic (concerning grammar) and semantic (concerning meaning) complexity. This will make it possible to identify difficulties with syntax and semantics and to document their impact on verb learning. We expect children with PPFTs to experience language impairment and a poor ability to learn new verbs compared to typically developing peers. Contrasts between children with children with PPFTs and siblings at 12 to 24 months post surgery will test this hypothesis, for different aspects of verb learning and verb processing (Aim 1). We believe that these impairments are associated with structural brain changes that result from treatment. Hence, relations between brain measures (white matter integrity, grey matter thickness) and language measure (verb processing and verb learning) will be studied at 12 months after surgery, to align with the end of the proton therapy treatment, and children with PPFTs will also be compared to the healthy siblings in anatomical measures (Aim 2). Finally, longitudinal changes in anatomical measures and language measures will be documented during the course of proton therapy (0 months to 12 months after surgery) and in the year after (12 months to 24 months after surgery), to study

both early and late effects of proton therapy. Across each of these two 12-month periods, the developmental change observed in anatomical and language measures in children with PPFTs will be compared to corresponding longitudinal data from healthy siblings (Aim 3).

**Study burden and risks**

The testing moments take place 0-2 months, 12 months, and/or 24 months after surgery. Patients will be required to participate in one session of 1 to 1.5 hours, at one to a maximum of three moments (depending on the moment of enrollment: see table 1 in the research protocol), followed by an MRI scan (T1-weighted images and diffusion MRI) at 12 months months after surgery. The language tests will be planned at the UMCG, at parents* home, or a lab at the university, as deemed most convenient to the family, after consultation with parents. There are no expected risks of administering these pen-and-paper or computer-based tests. However, the child may become tired, or feel unwell because of the post-surgical treatments that they are undergoing. This way, each assessment moment will be divided into smaller blocks of 15-30 minutes if necessary, and assessments will be interrupted flexibly to ensure the child*s well-being. The remaining measures, including neuropsychological test scores and MRI data (T1-weighted images and diffusion MRI) will be gathered as part of standard clinical practice, and shared with the researchers as agreed in data sharing agreements.

The healthy control group will complete a preliminary screening session of approximately 1h (to exclude the presence of language impairment), in addition to the same 1- to 1.5-hour session administered to patients. Both sessions will be planned in consecutive days, as it is expected that either the researcher or the participant may have to travel for data collection. Costs will be reimbursed. Furthermore, siblings will be invited for an MRI session as well, where the same MRI sequences administered to patients will be gathered. MRI has no known negative effects on health, and it is a standard brain imaging technique. There is a risk for individuals with any metal devices in their body, and these will not be allowed to participate. MRI involves lying still in a confined environment, which is difficult for children. During acquisition the scanner makes loud noises. Ear plugs will be provided, but noise is still audible and can be burdensome. For these reasons, the MRI acquisition will not be longer than 30 minutes with the session extending up to 1h (including 30 minutes of preparation time). Children and parents will be able to view an animated cartoon illustrating the procedures of the MRI session and children will go through a planned playful preparation to minimize any potential worries related to taking part in MRI acquisition. To minimize boredom, participants will be allowed to watch a movie during MRI acquisition, since no language tasks will be administered.

No benefit from participating in this research is anticipated for the healthy controls. However, their participation enables contrasting the results of

children with PPFTs and identifying aspects of verb processing and verb learning in which there is evidence of impairment. Such research findings will potentially provide clinicians with awareness of the need to assess verb processing and verb learning in this population.

Furthermore, the verb processing and verb learning tests that will be administered are currently undergoing a standardization process. This way, the scores of the participants can be contrasted to the normative data and shared with parents and clinicians, if desired, in the form of a short report. Such information may be used by the clinicians to help set further directions for language assessment and intervention for, for example, speech therapists directly involved in patient care.

Furthermore, this project aims to identify the cortical and subcortical regions that are at risk of radiation-induced damage, leading to language impairment. While this information will not be directly beneficial to those taking part in the present research, it may influence the development of radiation protocols tailored to spare those regions, and thus improve long-term outcomes and quality of life of survivors of PPFTs.

Although conducting this research with adults would be easier, posterior fossa tumors predominantly affect the pediatric population. Furthermore, the characterization of these children*s language abilities, and linguistic and neuroanatomical development during the course of post-surgical treatments cannot be assumed to match the same processes in an adult brain. This way, findings based on research with adults would not be directly transferable for the aims of the present research.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

## Inclusion criteria

Healthy sibling/control child:
- Age between 4;0 and 15;11 years at the time of enrollment
- Attend regular education

In order to be eligible to participate in this study as a child survivor of a PPFT, a subject must meet all of the following criteria:
- Age between 4;0 and 15;11 years at the time of enrollment
- Diagnosed with a posterior fossa tumor
- Referred to the UMCG proton therapy center for proton therapy treatment

## Exclusion criteria

• A diagnosis of Developmental Language Disorder (DLD, taalontwikkelingsstoornis), or suspected DLD (vermoeden van taalontwikkelingsstoornis of taalachterstand) preceding the onset of tumour-related symptoms
• History of neurodevelopmental disorders unrelated to the brain tumor
• History of psychiatric illness preceding the onset of tumour-related symptoms
• Intellectual disability preceding the onset of tumour-related symptoms (determined by a certified professional)
• Severe articulatory difficulties preceding the onset of tumour-related symptoms (determined by a certified professional)
• Uncorrected vision or hearing impairment preceding the onset of tumour-related symptoms (determined by a certified professional)

# Study design

## Design

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| 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

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| Recruitment status: | Pending |
| Start date (anticipated): | 01-06-2024 |
| Enrollment: | 112 |
| Type: | Anticipated |

# Ethics review

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| Approved WMO Date: | 13-06-2024 |
| 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 |
| --- | --- |
| CCMO | NL83231.042.23 |