The NEMO Project

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The primary objective is to examine whether changes over time in monitoring measures of cognition and behavior are associated with functional outcomes in pediatric oncology groups. Additional objectives are to examine trajectories, risk factors, and…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON21245

Source
Nationaal Trial Register

Brief title
NEMO

Condition

- Cognitive and attention disorders and disturbances

Synonym
Neurospychological monitoring, cognitive deficits, pediatric cancer

Health condition

Neuropsychological deficits as a consequence of childhood cancer

Research involving
Human

Sponsors and support

Primary sponsor: The Princess Máxima Centre
Source(s) of monetary or material Support: Core funding of PI

Intervention

Outcome measures

Primary outcome

Age-standardized performance on functional outcome measures (intelligence, memory, academics, school functioning, adaptive functioning, social-emotional functioning) and broader aspects of neuropsychological functioning (attention, executive function, working memory, processing speed, visual-spatial/motor, quality of life)

Secondary outcome

Secondary and tertiary study parameters/endpoints: Longitudinal trajectories on brief monitoring measures (1), clinical, biological, and psychosocial risk factors (2), mean performance and frequency of impairments on neuropsychological measures (3), and acceptability and feasibility of a monitoring program (4).

Study description

Background summary

Children with cancer may experience neuropsychological impairments and there is increasing evidence that many cancer groups are at-risk. Most studies have focused on long-term survivors, but some impairments are shown shortly after diagnosis which could be due to the disease itself, neurotoxicity of treatments (e.g., cranial radiation, intensive chemotherapies), stress, and/or fatigue. These results suggest that early monitoring is necessary across pediatric oncology groups, including brain tumors, solid tumors, and hematological malignancies. However, comprehensive evaluations are not feasible or necessary to conduct with all patients, and thus, brief measures that are sensitive to impairments are essential to follow patients and to implement services in a timely manner. Previous studies have only completed screening assessments at one time point and compared patient performance to group normative data, which may miss information due to variability across time or between patients. Rather, subtle changes within individual patients may occur over time, and these changes may be associated with functional outcomes such as intelligence or levels of independence. Along with consideration of bio-psycho-social risk factors, we hypothesize that changes in cognition or behavior over time can identify those who are most at-risk of functional impairments. This research will assist in developing neuropsychology monitoring programs, which will ultimately lead to earlier detection of and intervention for neuropsychological deficits in pediatric oncology. We also hypothesize that results may differ between treatment units, suggesting that each unit requires a tailor-made program.

Study objective

The primary objective is to examine whether changes over time in monitoring measures of cognition and behavior are associated with functional outcomes in pediatric oncology groups. Additional objectives are to examine trajectories, risk factors, and frequencies of neuropsychological impairment in early phases of treatment and survivorship as well as to determine the feasibility and acceptability of a neuropsychology monitoring program.

Study design

Single-center, prospective observational cohort study

Study burden and risks

This is a non-invasive, observational study and there is no substantial burden; if any, burden is related to time. Patients and parents/caregivers will be asked to complete neuropsychological tests and questionnaires at 5 time points across 2 years. The brief monitoring assessments are completed every 6 months (30 min for patients; 15 min for parents). More comprehensive testing will be completed at yearly intervals. Brain tumor patients and those referred for neuropsychological assessments will complete these tests as part of standard care; in these cases, it will take an additional 20-25 minutes for patients to participate in this study. If a patient is not seen for care, it will take 115-120 minutes for patients and 30-35 minutes for parents for these assessments. The most important tasks for our research questions are completed within the first 30-45 min of the assessment, and thus data is still obtained if testing needs to be shortened that day (i.e., due to fatigue, limited time). Furthermore, appointments will be combined with regularly scheduled appointments and there are opportunities for breaks or rescheduling the appointment if needed. Most questionnaires can be completed at home through the online KLIK portal. There are no anticipated risks for participation. One potential benefit is that parents will receive a summary of results from the comprehensive assessments (and will be referred for services when needed). Otherwise, there are no direct benefits for participation and results will be used to optimize care for future patients.

Contacts

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Eligibility criteria

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

Inclusion criteria

• New primary diagnosis of brain tumor, other solid tumor, or hemato-oncological condition • Age between 6 and 18 years old at diagnosis • Followed at the Princess Máxima Centre for Pediatric Oncology

Exclusion criteria

• No signed informed consent • Insufficient knowledge of the Dutch language to perform the neuropsychological assessment or complete questionnaires • Significant visual, motor, or developmental problems and thus alternative neuropsychological assessments would be needed (i.e., blindness, deafness, profound developmental delay) • Patients receiving palliative therapy or end-of-life care • Treating physician advises against inclusion

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Screening

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2021
Enrollment:	320
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	20-04-2021
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

ID: 52025
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9240
CCMO	NL76625.041.21
OMON	NL-OMON52025

Study results