The NEMO Project: Longitudinal Monitoring of Neuropsychological Outcomes in Pediatric Oncology

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON52025

Source
ToetsingOnline

Brief title
The NEMO Project

Condition

- Other condition

Synonym
cognitieve problemen, Neuropsychologische beperkingen

Health condition

Neuropsychologische problemen als gevolg van (de behandeling van) kinderkanker

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie
Source(s) of monetary or material Support: Core funding

Intervention

Keyword: Monitoring, Neuropsychological outcomes, Pediatric oncology

Outcome measures

Primary outcome

Age-standardized performance on functional outcome measures (intelligence, memory, academics, 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

(1) Latent longitudinal trajectories in performance on brief monitoring measures and their relationship with functional outcome measures, in other words, differences in functional outcome measures between groups with different cognitive trajectories. (2) The (strength of the) relationship between medical (e.g. pre-term birth, pre-morbid diagnoses, treatment) and psychosocial (e.g. socioeconomic status) risk factors and functional outcome measures. (4) Acceptability and feasibility of a monitoring program.

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 hemato-oncological conditions. 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). At the first and last assessment, more comprehensive testing will be completed. If a patient is not seen for care, these assessments will take an additional 115-120 minutes for patients and 30-35 more minutes for parents. Brain tumor patients and those referred for

neuropsychological assessments will complete these tests as part of standard care; in these cases, it will only take an additional 20-25 minutes for patients to participate in this study. 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

Public
Prinses Máxima Centrum voor Kinderoncologie

Heidelberglaan 25
Utrecht 3584 CS
NL
Scientific
Prinses Máxima Centrum voor Kinderoncologie

Heidelberglaan 25
Utrecht 3584 CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Children (2-11 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
• Primarily followed at the Princess Maxima Center for oncological care

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 or psychologist advises against inclusion

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-07-2021
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	21-01-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-02-2023
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21245
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL76625.041.21
Other	NL9240