ERNIE: Evaluating Response to Individualized Neuropsychological Intervention for Children with Brain Tumors

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The proposed study aims to examine the efficacy and process of an individualized (vs. standardized), comprehensive and family-centered neuropsychological intervention for pediatric brain tumor patients experiencing neuropsychological problems. The...

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

Summary

ID

NL-OMON56959

Source
ToetsingOnline

Brief title
ERNIE study

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC

Synonym
Neuropsychological deficits, pediatric brain tumor

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Individualization, Neuropsychological intervention, Pediatric Brain tumor

Outcome measures

Primary outcome

As noted above, the same study parameters are used for both the primary and secondary objectives and therefore are described together here. The difference is that the primary objective uses parameters from the post-intervention phase (T2); whereas the secondary objective uses parameters from all phases (T1/T2/T3).

The primary outcome measure will be goal attainment scaling (GAS), which is assessed through parent and patient interview. This method allows for scoring and tracking of an individual*s goals, but in a standardized format. Therefore, each participant has their own outcome measure, but the scaling is the same across participants to allow for statistical comparisons (i.e., T-score with M=50, SD=10). GAS scoring will be completed for both intervention groups, following established guidelines46.

Secondary outcome

Measurement of goal satisfaction through the Canadian Occupational Performance Measure (COPM).

Measurements of daily functioning, cognitive, socio-emotional, quality of life, and family/parental domains > Neuropsychological tasks and questionnaires. See protocol table 2 for measurement instruments.

Other parameters: Demographic/clinical data, medical history, family structure or support resources.

Tertiary research parameters/endpoints: process evaluation (recruitment, accuracy and early-stage data collection, implementation, experiences, and facilitators/barriers)

Study description

Background summary

With advances in treatment, 5-year survival rates for pediatric brain tumors are ~75% and thus the number of survivors is increasing worldwide. However, up to 50% of patients and survivors have neuropsychological difficulties that can impact their daily functioning and quality of life. For example, they may have attention or memory difficulties that impact their ability to complete schoolwork, interact with peers, or participate in activities across home, school, and community settings. Given the large impact on the brain tumor survivor and family, interventions that decrease the burden of these challenges are essential for improving quality of life for these children.

Previous intervention studies have attempted to improve elements of children*s functioning, such as through computerized cognitive training12 or medications to improve attention skills or cognitive-behavioral therapy to diminish anxiety symptoms. The current available interventions, however, have important limitations. For example, computerized training may not generalize to real-world tasks or parents may be hesitant to use medications for their child. Parents/caregivers have also not always been included within intervention studies, but they are essential partners to assist with treatment adherence and maintenance of skills. Also, the strongest evidence for efficacy with pediatric acquired brain injury groups have included the family/caregiver in the

intervention, which is consistent with systems theory and family-centered approaches. Finally, most interventions target one neuropsychological domain, but may lead to differences in outcomes given the variability between individual children and families. Therefore, these results suggest that a *one size fits all* intervention approach may not be suitable for pediatric brain tumor groups due to their complex and individual needs.

In recent years, there has been an increased focus on personalized or precision treatment, particularly in oncology and rehabilitation. Personalized treatment may also be important in pediatric or adult neuropsychological care, such as matching treatments to the personal characteristics of an individual patient and family. A family-centered and personalized approach that targets neuropsychological difficulties may be the most effective method for improving outcomes for children with complex needs, including pediatric brain tumors. Recent reviews also highlight the need for multicomponent interventions that include family members, however, this type of family-centered and comprehensive neuropsychological intervention has not been systematically evaluated.

This proposal will evaluate the efficacy and process of an individualized and comprehensive neuropsychological intervention compared to a standardized neuropsychological intervention, using a randomized control trial (RCT) design. Results will provide essential knowledge about how to target interventions on an individual level, which will help to improve daily functioning and quality of life in this vulnerable group of children.

Study objective

The proposed study aims to examine the efficacy and process of an individualized (vs. standardized), comprehensive and family-centered neuropsychological intervention for pediatric brain tumor patients experiencing neuropsychological problems. The intervention sessions will be completed within 3 months and will follow an individualized format (based on individually-designed program) or a standardized format (based on pre-determined program). This intervention offers both patients and parents tools for improving neuropsychological functioning, with the overall aim of improving quality of life of the child.

Primary Objective:
Immediate efficacy:
• The primary research question is whether an individualized neuropsychological intervention leads to greater changes in goal attainment and satisfaction and broader neuropsychological functioning, immediately after the intervention, when compared to a standardized intervention.

Secondary Objectives:
Maintenance:
• A secondary research question is whether an individualized neuropsychological

intervention leads to greater maintenance of changes in goal attainment and satisfaction and broader neuropsychological functioning when compared to a standardized intervention at the follow-up time point (12 months after inclusion).

Clinical significance:
• The other secondary research question if to examine the clinical significance of goal attainment and satisfaction and neuropsychological changes at the follow-up time point (12 months), including effect sizes and a reliable change index.

Tertiary Objectives:
Process:
• The tertiary research questions are to examine the process of the neuropsychological interventions, including the completion of intervention materials, dose, reach, costs of the intervention, experiences of families and interventionists, and facilitators and barriers to implementation.
• An exploratory analysis will examine whether there are factors that impact the completion of intervention materials, dose, reach, costs of the intervention, experiences of families and interventionists, and facilitators/barriers to implementation.

Study design

Monocenter prospective randomized controlled intervention study. The interventionists will not be blinded to the randomization, as this is not feasible with the current design. Patients will be blinded to the randomization/which group they are in.

Intervention

In both the individualized and standardized interventions, cognitive and socio-emotional domains are addressed, with a maximum of 3 goals per patient. The intervention team provides psycho-education and strategy training, enabling patients and parents to learn skills to enhance daily functioning. Both intervention groups follow a session schedule (6 sessions) over 3 months, partly conducted in the hospital and/or online (as needed). The individualized intervention is tailored to neuropsychological profiles and patient goals, whereas the standardized intervention group receives a predetermined set of modules. The focus is on explicitly linking intervention content to goals. This includes psycho-education about potential consequences of brain injury, followed by strategy training and practical application of learned skills. Materials are specifically compiled for the research based on existing programs.

Study burden and risks

The risks associated with participation can be considered negligible as the intervention is non-pharmacological, and uses elements from previously established psychological interventions. Neuropsychological tests and questionnaires are non-invasive and play-based for the youngest children. Burden is considered minimal, as questionnaires can be completed from home, testing schedules are flexible, and patients are provided with breaks when needed.

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)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

Age between 8-17 years old

Diagnosed with a primary brain tumor
Completed treatment for a primary brain tumor (patients who are considered *wait and see* and have not received treatment will also be eligible)
Experiencing cognitive problems (>=1SD below normative mean or >=1SD change over time on cognitive tests or cognitive questionnaires)
A parent/caregiver who they have regular contact with to participate with them

Exclusion criteria

No signed informed consent (either by patient and/or parents/legal guardian)
Cannot complete neuropsychological assessment or questionnaires because they do not speak/understand the Dutch language
Currently receiving palliative/end-of-life care
Currently receiving other neuropsychological treatment
• Severe developmental or psychiatric disorders and thus alternative interventions would be needed (e.g., autism spectrum disorder, schizophrenia, major depressive disorder)
Significant sensory, motor, or developmental problems and thus alternative neuropsychological assessments would be needed (i.e., blindness, deafness, profound developmental delay FSIQ <55)
• Treating physician or psychologist advises against inclusion

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-11-2024
Enrollment:	144

Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	20-08-2024
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL86240.041.24
Other	Volgt na METC goedkeuring