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An individualized neuropsychological intervention for children post brain tumor treatment

Submission date	Recruitment status	[ ] Prospectively registered
10/09/2024	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/10/2024	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/10/2024	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Children who survive brain tumors often have a hard time with thinking, emotions, or behavior. While there are treatments to help with these issues, most of them use the same approach for everyone, only focus on one type of thinking skill (such as memory), or don't involve the child's family in the treatment. This study wants to try a different approach by tailoring the treatment to each child's needs and including their families. We want to see if this helps improve the child's well-being. Specifically, we'll compare this personalized treatment to a one-size-fits-all method to see which is more effective and to understand the experiences of those involved and how easy or difficult it is to join the study.

Who can participate?
Patients aged 8-17 years, who have finished treatment for a brain tumor and have cognitive difficulties, along with a parent or caregiver.

What does the study involve?
Participants are randomly assigned to one of two groups: one receiving the individualized treatment and the other receiving the standardized intervention. Both groups receive six sessions of about 1 hour each over 3 months, either in-person or online. Both groups start the first session by setting goals for the treatment. The second session consists of a general psycho-education on the neuropsychological consequences of brain tumor (treatment). Sessions 3-5 consist of modules tailored to the child's needs/goals in the individualized arm, while the standardized arm follows preset modules addressing common neuropsychological symptoms after brain tumors. The sixth and last session is a concluding session. Sessions focus on psychoeducation, tips and strategy training to compensate for neuropsychological difficulties. Participants complete tests, questionnaires and interviews before, after, and 12 months after the intervention to assess changes in goal attainment, cognition, social-emotional, quality of life and family/parent domains.

What are the possible benefits and risks of participating?
The treatment techniques are non-invasive and have been used safely before. Participation

involves treatment and completing tests and questionnaires, which requires additional time. Some patients and their parents/caregivers complete neuropsychological tasks and questionnaires as part of standard care, which therefore minimizes the time burden. Participating in this study carries no expected risks. The treatment might help reduce the experience of neuropsychological problems. Patients/parents receive a summary of assessment results and appropriate referrals if needed. Taking part in this study will help us learn more about how to treat neuropsychological problems after a brain tumor.

Where is the study run from?
Princess Máxima Center Utrecht (The Netherlands).

When is the study starting and how long is it expected to run for?
July 2023 to October 2027

Who is funding the study?
The Dutch Cancer Society (DCS; in Dutch: 'KWF Kankerbestrijding') (The Netherlands)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PN21ERN/NL86240.041.24

Study information

Scientific Title
ERNIE: Evaluating Response to iNdividualized neuropsychological IntervEntion for children with brain tumors

Acronym
ERNIE

Study objectives
The efficacy of individualized versus standardized neuropsychological interventions for children post brain tumor treatment has not been studied before. Based on previous research comparing individualized/tailored intervention approaches to standardized intervention approaches, we expect that the individualized intervention leads to greater changes in goal attainment than the standardized intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/08/2024, Netherlands Medical Ethics Committee (Medisch-Ethische Toetsingcommissie NedMec) (Heidelberglaan 100, Utrecht, 3584 CX, Netherlands; +31 (0)88 7556376; metc@nedmec.nl), ref: 24-131/G; NL86240.041.24

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied
Neuropsychological problems in children who finished treatment for a primary brain tumor

Interventions
In this RCT, participants and their parents will be randomized using an online tool to the individualized intervention arm or standardized intervention arm. Participants will be blinded to their treatment condition.

Both intervention arms consist of six sessions of approximately 1 hour over 3 months, either in-person or online, depending on preference. Trained psychologists serve as interventionists, with support from a PhD student. Both intervention groups will start the first session with goal setting followed by the second session that consists of a general psycho-education module. Sessions 3-5 will consist of modules tailored to the child's needs/goals in the individualized arm, while the standardized arm follows preset modules addressing common neuropsychological symptoms after brain tumors. The sixth and final session of the neuropsychological intervention will serve as a concluding session, encompassing a summary of the content covered throughout the intervention, facilitating closure, and providing an opportunity for discussion and reflection.

Sessions focus on psychoeducation tips and strategy training (adapted from previous intervention studies), promoting patient and parent collaboration.

Intervention Type
Behavioural

Primary outcome(s)
Goal attainment is measured using Goal Attainment Scaling (GAS) at baseline, 3 months and 12 months follow-up

Key secondary outcome(s))
1. Neuropsychological assessment tasks:
1.1 Estimated Intelligent Quotient (IQ) measured using the Vocabulary and Matrix Reasoning subtests from Weschler Intelligence Scale for Children-V (WISC-V)/Weschler Adult Intelligence Scale-IV (WAIS-IV) at baseline and 12 months follow-up
1.2 Working memory measured using the Digit Span from WISC-V/WAIS-IV at baseline and 12 months follow-up
1.3. Processing speed measured using the Coding from WISC-V/WAIS-IV at baseline and 12 months follow-up
1.4. Executive functioning measured using the subtests Road Walking from the Intelligence and Development Scales-2 (IDS-2) at baseline and 12 months follow-up
1.5. Memory measured using Rey Auditory Verbal Learning Test (RAVLT) at baseline and 12 months follow-up
1.6. Sustained attention measured using Continuous Performance Test-3 (CPT-3) at baseline and 12 months follow-up
1.7 Social functioning measured using IDS-2 Socially Competent Behavior task at baseline and 12 months follow-up

2. Questionnaires filled out by parents and/or patients:
2.1 Adaptive behavior measured by the Adaptive Behavior Assessment System – Third Edition (ABAS-3) at baseline, 3 months and 12 months follow-up
2.2 Executive functioning in daily life measured by the Behavior Rating of Executive Function-2 (BRIEF-2) at baseline, 3 months and 12 months follow-up
2.3 Fatigue measured by the Pediatric Quality of Life Inventory Multidimensional Fatigue Scale (PedsQL-MFS) at baseline, 3 months and 12 months follow-up
2.4 Emotional problems measured by the Patient-Reported Outcomes Measurement Information System (PROMIS) Anxiety and Depressive Symptoms Short Forms 3.0 at baseline, 3 months and 12 months follow-up
2.5 Social functioning measured by the PROMIS Peer Relationships short form 3.0 at baseline, 3 months and 12 months follow-up
2.6 Parental stress measured by the Distress Thermometer for Parents (DT-P) at baseline, 3 months and 12 months follow-up
2.7 Socioeconomic status, birth, developmental, psychiatric, and school history measured by a self-developed questionnaire at baseline

3. Demographic and clinical data obtained through medical records at baseline

GAS and questionnaires at 3 months (directly post-intervention) are measures for the primary objective. GAS, questionnaires and neuropsychological tasks at 12 months follow-up are measures of the secondary objective.

4. Process evaluation using researcher records of implementation (completion of intervention materials, dose, reach, costs) and other facilitators/barriers to implementation and questionnaires assessing experiences of families/interventionists, at 3 months.

Completion date
01/10/2027

Eligibility

Key inclusion criteria
1. Age between 8-17 years old
2. Diagnosed with a primary brain tumor
3. Completed treatment for a primary brain tumor (patients who are considered “wait and see” and have not received treatment will also be eligible)
4. Experiencing cognitive problems (≥1SD below normative mean or estimated IQ [EIQ]) on ≥2 scores, including WISC-V/WAIS-IV, IDS2, CPT3, 15WT tests and/or self- or proxy-reported PedsQL Fatigue or BRIEF-2 questionnaires)
5. A parent/caregiver who they have regular contact (in order to participate in the intervention with them)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
17 years

Sex
All

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

Date of first enrolment
01/10/2024

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
Princess Máxima Center for Pediatric Oncology
Heidelberglaan 25
Utrecht
Netherlands
3584 CS

Sponsor information

Organisation
Princess Máxima Center

ROR
https://ror.org/02aj7yc53

Funder(s)

Funder type
Charity

Funder Name
KWF Kankerbestrijding

Alternative Name(s)
Dutch Cancer Society, Dutch Cancer Society (KWF Kankerbestrijding), KWF, DCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes