Computer training and strategy instruction for children and adolescents with acquired brain injury.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19870

Source
NTR

Brief title
BrainLevel

Health condition

Acquired brain injury, Traumatic brain injury, Cognitive Rehabilitation, Children, Adolescents,

Niet-aangeboren hersenletsel, Traumatisch hersenletsel, Cognitieve revalidatie, Kinderen, Jongeren, Adolescenten

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Johanna KinderFonds, Stichting Rotterdams Kinderrevalidatie Fonds Adriaanstichting, de Cornelia-Stichting

Intervention

Outcome measures

Primary outcome

Three cognitive tests have been selected as primary outcome measures to assess change in attention (score on d2), working memory (score on Corsi Block-Tapping Test), and executive functioning (score on Concept Shifting Task). The main study parameters are the change in performance from baseline measurement (T0) to post intervention measurement (T1, i.e., 6 to 8 weeks after T0) and the change from T1 to T2 (follow-up after 3 months) on each of these three tests.

Secondary outcome

Cognitive functioning:

1. Intelligence: WISC-III short form

2. Attention: Coding (WISC-III); Five to Fifteen questionnaire (parent and teacher version)

3. Working memory: Digit Span (WISC-III)

4. Executive functioning: Stop Signal Reaction Task; Verbal Fluency; Behavioral Rating Inventory of Executive Functioning (parent version).

Psychosocial functioning:

1. Participation: Child and Adolescent Scale of Participation (parent and child version)

2. Family functioning: Family Assessment Device - General Functioning (parent version)

3. Quality of life: Pediatric Quality of Life Inventory - Generic core scale and Multidimensional fatigue scales (parent and child version).

Study description

Background summary

Children and adolescents with acquired brain injury (ABI) frequently report problems with cognitive functioning and consequently problems with psychosocial functioning. While these problems are usually targeted with cognitive rehabilitation, evidence from well-designed studies into effectiveness of cognitive rehabilitation is lacking in this population. Computer-based cognitive retraining (CBCR) is a promising cognitive rehabilitation method, but has been insufficiently investigated in children and adolescents with ABI. The aim of the current study is to target cognitive functioning (i.e., attention, working memory, and executive functioning,) and consequentially psychosocial functioning (i.e., participation, family functioning and quality of life) of children and adolescents (age 8–18) with ABI by use of a CBCR combined with explicit strategy instruction. The study has a multicentre pretest-

posttest trial design. There will be three time points of measurement: baseline (T0) before the start of the intervention period, post intervention (T1), and follow-up three months after the intervention (T2). Children and adolescents with ABI (n=50) who are at least 6 months post-injury and are experiencing cognitive problems will be recruited from rehabilitation centres and specialized schools during approximately 4 years (January 2016– December 2020).
All participating children and adolescents will be offered a 6–week CBCR program targeting a wide range of cognitive functions (i.e., attention, working memory, and executive functioning) combined with explicit strategy instruction. Participants train 5 times a week for approximately 30 minutes and attend 45 minutes of explicit strategy instruction per week. Three cognitive tests have been selected as primary outcome measures to assess change in attention (score on d2), working memory (score on Corsi Block-Tapping Test), and executive functioning (score on Concept Shifting Task). The main study parameters are the change in performance from baseline measurement (T0) to post intervention measurement (T1, i.e., 6 to 8 weeks after T0) on each of these three tests. For a broad overview of cognitive functioning after the intervention period, additional cognitive tests have been selected as secondary outcomes. Furthermore, subjective cognitive functioning (as measured with questionnaires) and psychosocial functioning (i.e., participation, family functioning and quality of life) of children and adolescent with ABI are considered secondary study parameters.

Study objective

Children and adolescents with acquired brain injury who receive the computer-based cognitive retraining combined with the explicit strategy instruction will show significantly more improvement of cognitive functioning (i.e., attention, working memory, and executive functioning) and psychosocial functioning (i.e., participation, family functioning and quality of life) compared to children who only receive care as usual.

Study design

Baseline before the start of the intervention period (T0);

Post intervention (T1);

Follow-up three months after the intervention (T2).

Intervention

All participating children and adolescents will receive care as usual. In addition, participants in the intervention group will be offered a 6–week CBCR program targeting a wide range of cognitive functions (i.e., attention, working memory, and executive functioning) combined with explicit strategy instruction. Participants train 5 times a week for approximately 30 minutes and attend 45 minutes of explicit strategy instruction per week.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 8 and 18 years;

2. Diagnosed with ABI (e.g., traumatic brain injury, brain tumour, stroke, encephalitis, meningitis, and hypoxia);

3. At least 6 months post injury;

4. Experiencing problems with at least one of the to be trained cognitive functions (i.e., attention, working memory, or executive functioning);

5. Patient in a rehabilitation centre or student at a specialized school;

6. Able to control the arrow keys of a keyboard and/or to use a computer mouse and visually able to perceive a complete screen and to adequately process the stimuli of the computer games and the neuropsychological tests;

Exclusion criteria

1. General level of intelligence lower than 80;

2. Co-morbidity: extreme sensibility for visual stimuli, epilepsy, depression, or other health complaints or learning disabilities which can negatively influence the participation in the present study;

3. Previously present brain damage (i.e., already suffered a brain damage some years ago) or central nervous system disease (e.g., epilepsy);

4. Has previously trained with a CBCR program

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2016
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47636
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5504
NTR-old	NTR5639
CCMO	NL54523.068.15
OMON	NL-OMON47636

Study results