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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19870

Bron
NTR

Verkorte titel
BrainLevel

Aandoening

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

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

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Johanna KinderFonds, Stichting Rotterdams Kinderrevalidatie Fonds Adriaanstichting, de Cornelia-Stichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Post intervention (T1);

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47636
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten