Computer-based cognitive retraining (CBCR) combined with explicit strategy instruction for children and adolescents with acquired brain injury (ABI)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47636

Source
ToetsingOnline

Brief title
CBCR after ABI

Condition

- Other condition

Synonym
ABI, brain damage

Health condition

niet-aangeboren hersenletsel

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Johanna KinderFonds;Cornelia Stichting en Rotterdams Kinderrevalidatie Fonds Adriaanstichting

Intervention

Keyword: acquired brain injury, children, cognitive rehabilitation, computer-based cognitive retraining

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) on each of these three tests.

Secondary outcome

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 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.

Study objective

The aim 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.

Study design

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).

Intervention

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.

Study burden and risks

There are no known risks associated with participation in this study. The experimental intervention offered to participants in the intervention group has potential to improve cognitive and psychosocial functioning. Neuropsychological assessment and filling in questionnaires is in general not experienced as stressful or invasive.

Contacts

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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)
Elderly (65 years and older)

Inclusion criteria

- Age between 8 and 18 years
- Diagnosed with ABI (e.g., traumatic brain injury, brain tumour, stroke, encephalitis, meningitis, and hypoxia).
- At least 6 months post injury
- Experiencing problems with at least one of the to be trained cognitive functions (i.e., attention, working memory, or executive functioning)

Exclusion criteria

- General level of intelligence lower than 80 (important with regard to the reliability and validity of the test administration)
- Unable to perceive visual stimuli and/or control the arrow keys of a keyboard/ a computer mouse
- Previously trained with a CBCR

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2016
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	16-03-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-05-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	19-07-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-07-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-09-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-10-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-12-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-01-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-02-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 19870
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54523.068.15
OMON	NL-OMON19870