Working memory training in children with neuropsychiatric disorders and borderline intellectual functioning

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1. To investigate the efficacy of Cogmed working memory training in reducing behavioral symptoms in children with neuropsychiatric disorders and borderline intellectual functioning.2. To investigate whether WM training improves neurocognitive...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36703

Source
ToetsingOnline

Brief title
WMT in children with neuropsychiatric disorders and BIF

Condition

- Other condition
- Developmental disorders NEC

Synonym
ADHD and Autism spectrum disorders, neuropsychiatric disorders

Health condition

neuropsychiatrische stoornissen en een ontwikkelingsachterstand

Research involving
Human

Sponsors and support

Primary sponsor: Karakter
Source(s) of monetary or material Support: 32.915;- euro subsidie is toegekend door het Antonia Wilhelminafonds (onderdeel van het Fonds Psychische Gezondheid)

Intervention

Keyword: borderline intellectual functioning, neuropsychiatric disorders, working memory training

Outcome measures

Primary outcome

-The measured difference in behavioral problems before and after training

-The measured difference in neurocognitive functioning before and after training

-The measured difference in schoolachievement before and after training

Secondary outcome

Side effects (headache, extreme tiredness, sleepingproblems).

Study description

Background summary

It is important to develop evidence-based treatments for children with borderline intellectual functioning (BIF; 70disorders, because regular cognitive-behavioural therapies are often to complex
due to lower intellectual abilities and less developed adaptive skills. This group is of particular interest, because 40% of the children with an IQ between 70 and 85 have a psychiatric disorder. A total of approximately 14,8% of this group of children are found to meet the DSM-IV symptom criteria for ADHD and 1,5% for pervasive developmental disorder not otherwise specified (PDD-NOS; Dekker & Koot, 2003).
Working memory training has been shown effective in children with attention-deficit/hyperactivity disorder. Previous studies have found significant improvements in behavioural- and neurocognitive problems, i.e. attention, hyperactivity-impulsivity, visual and verbal working memory, complex reasoning skills, visual-spatial skills and problem solving skills (Klingberg et al., 2005; Gibson et.al., 2006). Working memory training has also been shown

effective in other populations, including children with acquired brain injuries (Van *t Hooft et.al., 2007) and children with mild intellectual disabilities (MID; 50found to improve as well as the academic achievements (van der Molen, et al., 2010). A pilot study on the effects of working memory training in children in special education classes showed improvements in working memory, problem solving abilities and academic achievements up to six months after training (Dahlin, Myrberg and Klingberg; data presented at the Scandinavian conference of dyslexia, 2005). Results of these previous studies indicate positive effects of working memory training in children with neuropsychiatric disorders and lower intelligence. However, the effects of working memory training have not yet been studied in a stringent defined group of children with borderline intellectual functioning (BIF; 70Attention-deficit/hyperactivity disorder and Autism spectrum disorders) .
Cogmed© working memory training (Klingberg et al., 2005) is at this point one of the most promising neurocognitive training possibilities for children with ADHD (and related disorders), available in the Netherlands. In this training program (working) memory tasks will be trained daily on a computer. So far, Cogmed has not been studied on effectiveness and safety (regarding side effects) in a child psychiatric population with bordeline intellectual disabilities (BIF). One of the benefits of a cognitive training over medication might be the absence of (serious) side effects. However, this has not been studied in children with neuropsychiatric disorders and BIF.
This study will investigate the effectiveness and safety of working memory training in this double-diagnosis group in a double blind randomized controlled trial. If the Cogmed working memory training will be proven effective in this group of children, as shown by improvements in working memory ánd in behavioral symptoms, this treatment may contribute to a better quality of life of the patients and their families.

Study objective

1. To investigate the efficacy of Cogmed working memory training in reducing behavioral symptoms in children with neuropsychiatric disorders and borderline intellectual functioning.
2. To investigate whether WM training improves neurocognitive functioning and academic achievements in children with neuropsychiatric disorders and borderline intellectual functioning.
3. To investigate the safety of the Cogmed working memory training in this group of patients, in terms of side effects (headache, extreme tiredness, sleepingproblems).

Study design

In a double blind randomized controlled trail, two groups, each containing 50 children, will be compared. The duration of the training for three groups is 30 minutes, 5 days a week for 5 weeks. Before and after the training, all children

will undergo a neurocognitive assessment (pre- en post- assessment). In the week after the last session, the post-assessment will be done and an evaluation of the training will take place. Three months after the last training session there will be a follow-up.
a) One group will be treated with the Cogmed© working memory training, version R/M.
b) One group will be treated with a control version of Cogmed. The control training version is exactly the same and looks the same as the WM training that will be used in the treatment condition, but with a lower WM load (i.e., less number of items to be remembered). In the control version, the level of difficulty will still depend on how well the child performs, but there is a limit of two to three items to show up, so that the child is not able to get to a higher level than 3. Previous studies on Cogmed Working Memory training program for children above 7 years old have shown that this version functions well as a control condition (Klingberg et al., 2002a; Klingberg et al., 2005a). When asked after completing the training, children all reported they were convinced they had been training in the treatment group. Both conditions have been developed by Cogmed Cognitive Medical Systems AB (Stockholm, Sweden) and translated by BeterBrein, the official Licensed Practice in the Netherlands for Cogmed, represented by Kathryn Ralph (Kathryn.Ralph@Pearson.com, for more information).

Intervention

Cogmed© working memory training (Klingberg et al., 2005)

Study burden and risks

Risks will be considered minimal. Possible minor effects as headache or sleeping problems will be assessed before, halfway and after the training

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Children aged between 10 years/0 months and 13 years/11 months, known in psychiatric health care and/or special education.
- Neuropsychiatric disorders (ADHD, ASD, or a combination of those two, possibly in combination with comorbid ODD), classified by the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, 2000).
- IQ score between 70 and 85 (BIF).
- Access to a PC with Windows Vista or Windows XP with internet connection and speakers (at home or school).

Exclusion criteria

- Currently intensive (i.e. weekly) individual or group psychotherapy.
- Regular use of other medication (stimulants / neuroleptics). When medication is used for ADHD, this isn*t a exclusion criteria in case of *room for improvement*.
- Diagnosis of one or more of the following comorbid psychiatric disorders:
o Major depression
o Bipolar disorder
o Psychotic disorder
o Chronically motor tic disorder or Gilles de la Tourette
o Conduct disorder
o Eating disorders
o Anxiety disorders
- Neurological disorders (e.g. epilepsy) in the recent two years.
- Cardiovascular disease currently or in the past.

- Serious motor and/or perceptual handicap.
- Participation in another clinical trail simultaneously.
- Insufficient motivation to follow the training.
- Medical illness which needs medical treatment.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-07-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 20558
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL32435.091.10
OMON	NL-OMON20558