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

Gepubliceerd: 07-06-2011 Laatst bijgewerkt: 15-05-2024

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...

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

Samenvatting

ID

NL-OMON20558

Bron
NTR

Verkorte titel
WORM-ID

Aandoening

Children with neuropsychiatric disorders and borderline intellectual functioning

Ondersteuning

Primaire sponsor: Karakter kinder- en jeugdpsychiatrie
Overige ondersteuning: Fonds Psychische Gezondheidszorg (subdivisie Antonia Wilhelmina Fonds)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The measured difference in behavioral problems before and after training;
2. The measured difference in neurocognitive functioning before and after training;
3. The measured difference in schoolachievement before and after training.

Study procedure from A-Z:
In the following part, we will describe the whole study procedure from start to follow- up, including the rationale for the proposed measurements. In sum, there will be a selection phase, pre- and post-assessments and a follow-up. Note that an assessment in our “clinical care as usual” includes;
1. A clinical interview with the parents and the child (an intake);
2. A structural developmental interview;
3. A comprehensive set of questionnaires;
4. A neuropsychological assessment with an average duration of 2 – 2 ½ hours;
5. An appointment for instruction of the training;
6. An appointment for evaluation.
So in sum, the post-assessment and the follow-up will be extra for the research project compared to our daily care as usual. To be comprehensive, below, we will describe the whole procedure.

Part one: Selection phase.
Scales and Questionnaires.
An extensive clinical diagnostic procedure including a structural developmental interview and a clinical interview with the parents and the child, supervised by a child and adolescent psychiatrist will be scrutinized by a clinical diagnostic procedure including:
1. In case of ADHD and/or ASS, the ADHD and/or ASS criteria according to the DSM-IV will be checked and filled out by an experienced psychologist;
2. For assessment of other comorbid psychiatric disorders, the Diagnostic Interview Schedule for Children (DISC-IV), a highly structured diagnostic instrument designed for use by non-clinicians (Berument et.al., 1999) will be included;
3. The intellectual disabilities will also be checked before participation, through five subtests of the WISC-III-NL (Information, Vocabulary, Picture Completion, Block Design, Digit Span), (Kort et al., 2005).

Part two: Pre-treatment-assessment.
Scales and Questionnaires.
The following parameters will be assessed before treatment (45 minutes):
1. For baseline measurement of clinical improvement, the investigator will fill out the Clinical Global Impression-Global severity scale (CGI-S), a widely used instrument to assess clinical effects in intervention studies (Shaffer et.al., 2000);
2. To evaluate psychosocial functioning of the child, the Children’s Global Assessment Scale (C-GAS; Shaffer et.al., 1983) will be completed;
3. The Vragenlijst voor Inventarisatie van Sociaal gedrag van Kinderen (VISK; Luteijn, Minderaa, & Jackson, 2002) in case of ASS, and the ADHD rating scale in case of ADHD will be filled out by parents and teacher;
4. For baseline measurement of improvement of executive functioning, the Behavior Rating Inventory of Executive Function checklist (BRIEF; Smidts et al., 2009), will be filled in by the parents and teachers;

5. A side-effects checklist will be filled in.

Neurocognitive functioning:
We will test 3 domains of neurocognitive functioning and academic achievements. This will take about 2 to 2 ½ hours. After each training session training children will be questioned about the quality of training (how much fun was it to do) and about their motivation, both scaled from 0 - 10.

1. (Working) Memory (WM):
A. Visual (spatial) short term memory: Blok recall, (Pickering et al., 2001) & Visual patterns test, (Della Sala, Gray, Baddeley, & Wilson, 1997);
B. Verbal short term memory: Digit recall, (Pickering et al., 2001) & Nonword list recall, (Pickering et al., 2001);
C. Visual (spatial) working memory: Spatial span, (Alloway, 2007);
D. Verbal working memory: Listening recall, (Pickering et al., 2001) & Backward digit recall, (Pickering et al., 2001).
2. Executive Functioning (EF):
A. Response inhibition: Go-Nogo, Amsterdamse Neuropsychologische Taken (GNG/ANT; De Sonneville, 2009);
B. Attention: Sustained Attention Dots, Amsterdamse Neuropsychologische Taken (SAD/ANT; De Sonneville, 2009).
3. Fluid intelligence (non-verbal): Raven Standard progressive matrices, (Raven, Court, & Raven, 1996);
4. Academic achievements: Tempo Toets Rekenen (arithmetic), (TTR; De Vos, 1992), Brus 1 minuut (reading), (Brus & Voeten, 1973) & Story recall (daily memory), (Van der Molen, 2007).

Part three: Post-treatment assessment.
We will repeat the following questionnaires and scales and the neurocognitive tasks of the pre-treatment 1 week after the last session: ADHD and/or Autism spectrum disorder criteria according to DSM-IV, the VISK and ADHD rating scale, C-GAS, CGI-C and BRIEF.
There will be an evaluation for parents and children to discuss experiences of the treatment and answering questions with the researchers.

Part four: Follow-up.
To determine if treatment effects are lasting, decrease or increase over time, we will perform a follow-up at 6 months after the end-point of study to observe possible clinical improvements by assessing the severity of behavioral problems through the same selection of scales and questionnaires used in the post-treatment assessment. Also a selection of neurocognitive measures will be assessed: verbal and visual working memory, fluid intelligence (Raven), attention and academic achievements (see above for details of the measures).

Toelichting onderzoek

Achtergrond van het onderzoek

It is important to develop evidence-based treatments for children with borderline intellectual functioning (BIF; 70
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; 50
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.

Doel van het onderzoek

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).

Onderzoeksopzet

Start pilot august 2011.

Onderzoeksproduct en/of interventie

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

Working memory training procedure: In a double blind randomized controlled trail, two groups, each containing 50 children, will be compared. One group will be treated with the Cogmed© working memory training, version R/M. One group will be treated with a control version of Cogmed. The duration of the training for the groups is 30-45 minutes, 5 days a

week for 5 weeks. The program includes visuospatial WM tasks (e.g., remembering the position of objects in a 4x4 grid), as well as verbal tasks (remembering phonemes, letters, or digits). Responses are made by clicking on displays using the computer mouse. The children will perform a variable amount of trials each training, depending on the level of the child. Difficulty level is automatically adjusted on a trial-by-trial basis to match the WM span of the child. The difficulty level will always be on the boarder of ability of the child. Compliance control will be extended by frequently uploading the performance in a log file by the aides to the personal coach. The average compliance rate (based on all age groups: toddlers, school children, adults) is around 95 %.

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.

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. Six months after the last training session there will be a follow-up. 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).

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Children aged between 10 years/0 months and 13 years/11 months, known in psychiatric health care and/or special education;

2. 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);

3. IQ score between 70 and 85 (BIF);

4. Access to a PC with Windows Vista or Windows XP with internet connection and speakers (at home or school).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Currently intensive (i.e. weekly) individual or group psychotherapy;

2. 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';

3. Diagnosis of one or more of the following comorbid psychiatric disorders:

A. Major depression;

B. Bipolar disorder;

C. Psychotic disorder;

D. Chronically motor tic disorder or Gilles de la Tourette;

E. Conduct disorder;

F. Eating disorders;

G. Anxiety disorders.

4. Neurological disorders (e.g. epilepsy) in the recent two years;

5. Cardiovascular disease currently or in the past;

6. Serious motor and/or perceptual handicap;

7. Participation in another clinical trail simultaneously;

8. Insufficient motivation to follow the training;

9. Medical illness which needs medical treatment.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2011
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-06-2011

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36703
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2798
NTR-old	NTR2939
CCMO	NL32435.091.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36703

Resultaten

Samenvatting resultaten
N/A