Working Memory Training in children with Neuropsychiatric Disorders and Mild to Borderline Intellectual Disabilities

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To investigate the efficacy of a less intensive but more prolonged Cogmed © RM WMT (including active personalized coaching and feedback) in reducing behavioral symptoms and improving neurocognitive functioning and academic achievements in children...

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

Summary

ID

NL-OMON43683

Source
ToetsingOnline

Brief title
WMT in children with neuropsychiatric disorders and MBID

Condition

- Other condition
- Cognitive and attention disorders and disturbances

Synonym
ADHD, Autisme Spectrum Disorder

Health condition

neuropsychiatrische stoornissen en een licht verstandelijke beperking

Research involving
Human

Sponsors and support

Primary sponsor: Karakter
Source(s) of monetary or material Support: Antonia Wilhelmina fonds

Intervention

Keyword: borderline intellectual functioning, mild intellectual functioning, neuropsychiatrisc disorders, working memory training

Outcome measures

Primary outcome

-The scores in behavioural problems (VISK, AVL, BRIEF, APQ) before and after

training

-The scores in neurocognitive functioning (Working memory: spatial span,

backward digit recall, listening recall; Executive functioning: Sustained

Attention Dots, Go-Nogo; Understanding instruction: begrip van instructie)

before and after training.

-The scores in school achievement (Arithmetic:Tempo Toets Rekenen; reading:

Brus 1 minuut) before and after training.

Secondary outcome

not applicable

Study description

Background summary

Working memory training (WMT) has been shown to offer therapeutic benefits to
both patients with ADHD and patients with Mild to Borderline Intellectual
Disabilities (MBID;60Van der Molen et al., 2010). However, additional research is needed since most
studies failed to find robust evidence for transfer effects of WMT to
behavioral symptoms and daily functioning (Chacko et al., 2103; Melby-Lervag &

Hulme, 2013). Furthermore, studies that included a placebo control group did not show treatment benefits of WMT over a placebo training, in line with the pilot results of our own study in children with neurodevelopmental disorders and MBID (Roording-Ragetlie et al., ongoing research [METC protocol nr NL32435.091.10]; Van der Donk et al, submitted; Van Dongen-Boomsma et al., 2014). Due to the inclusion of a placebo-controlled version and the double-blind design of these studies, children received non-specific coaching (not based on their actual training performance). Active coaching based on personal training results -equal to coaching in clinical practice- might enlarge the efficacy of Cogmed WMT (Van Dongen-Boomsma et al., 2014). In the present study, therefore the effect of active, personalized coaching and feedback during the Cogmed WMT will be examined in children with MBID and neuropsychiatric disorders. Since children with MBID may have a lower WM capacity than children with an average intelligence level, they will receive a less intensive and more prolonged Cogmed WMT. A lower WM baseline at start may influence daily duration of the training and coherent motivation (overall training is more difficult for this population). Prolonged but less intensive training might fit these children better (Richtlijn Effectieve Interventies LVB, 2011).

Study objective

To investigate the efficacy of a less intensive but more prolonged Cogmed © RM WMT (including active personalized coaching and feedback) in reducing behavioral symptoms and improving neurocognitive functioning and academic achievements in children with MBID and neuropsychiatric disorders.

Study design

Double-blind randomised controlled intervention study

Intervention

Two groups, each containing 25 children, will receive a less intensive but prolonged Cogmed© WMT at home or at school, version R/M for 8 weeks, 4 days a week, 35 minutes a day. This is a prolonged version of the original 5 week-Cogmed training, 5 days a week, 50 minutes a day. One group will receive weekly active personalized coaching and feedback based on their actual performance during the Cogmed training. This active coaching is part of the regular Cogmed training in clinical practice. The other group will not receive personalized coaching and feedback (only general non-personalized coaching). Before and after training, both groups will undergo a neurocognitive assessment (pre- and 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 a follow-up will take place.

Study burden and risks

Risks will be considered minimal. Possible minor effects as headache or sleeping problems will be assessed in recent study (protocol NL32435.091.10).

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

- Childeren between 10 years/0months and 13 years /11months, 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, 2013).
- IQ score between 60-85
- Access to a PC with Windows Vista or Windows XP with internet connection and speakers (at home or at school).

Exclusion criteria

1. Treatment at an inpatient or day treatment clinic.
2. Regular use of other medication than for ADHD or ASD.
4. If medication for ADHD/ASD is used and *room for improvement for ADHD symptoms* is absent
3. Diagnosis of one or more of the following comorbid psychiatric disorders (checked by DISC-IV):
- Major depression
- Bipolar disorder
- Psychotic disorder
- Conduct disorder
- Anxiety disorder
- 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 trial simultaneously.
- Insufficient motivation to follow the training.
- Medical illness which needs medical treatment.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-09-2016
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	14-07-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-07-2016
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL52647.091.15