Working Memory (WM) training: A randomised controlled treatment study in young ADHD children.

Published: 08-12-2008
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Objective: 1) To investigate the efficacy of WM training in reducing behavioral symptoms in young children with ADHD.2) To investigate whether WM training improves neurocognitive functioning in young children with ADHD.3) To investigate whether WM...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON32875

Source
ToetsingOnline

Brief title
Working Memory training in ADHD children

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD, attention disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Smartmix fonds

Intervention

Keyword: ADHD, children, Working memory training

Outcome measures

Primary outcome

Main study parameter/endpoint: ADHD-DSM-IV rating scale rated by the

investigator.

Secondary outcome

Neurocognitive functioning in young children with ADHD

Neural functioning in young children with ADHD

Study description

Background summary

Rationale: WM training has been shown to offer therapeutic benefits to patients with ADHD in several studies, but methodological shortcomings indicate that additional research is needed. This study is designed to examine the efficacy of WM training in a scientific rigorously way in young ADHD children.

Study objective

Objective:
1) To investigate the efficacy of WM training in reducing behavioral symptoms in young children with ADHD.
2) To investigate whether WM training improves neurocognitive functioning in young children with ADHD.
3) To investigate whether WM training improves neural functioning in young children with ADHD.

Study design

Double-blind randomised controlled treatment study.

Intervention

Intervention: 50 subjects receive 25 sessions WM training and 50 subjects receive 25 sessions of the control version of WM training.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Risks or side-effects are not expected. The burden for the subjects consists of an intake, pre- and post-treatment assessments, the training itself consisting of 25 sessions for 15 minutes, an evaluation and a follow-up. The intake, pre-assessment, training and evaluation carry the same burden as treatment as usual. The benefit involves of the a priori chance of positive effect of the WM training on ADHD symptoms. Because ADHD is primarily a psychiatric disorder of childhood, children will form the target population of the present study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Age between 4 years/6 months and 7 years/4 months
Diagnosis ADHD, classified by the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, 2000)
A full scale IQ > 80 ;Psychopharmaca- naïve or -free;Access to a PC with Windows Vista or Windows XP with internet connection and speakers at home

Exclusion criteria

Currently intensive (i.e. weekly) individual or group psychotherapy
Regular use of other medication
Comorbid psychiatric disorders other than Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS).
Neurological disorders (e.g. epilepsy) currently or in the past
Cardiovascular disease currently or in the past
Serious motor or perceptual handicap
Participation in another clinical trial simultaneously
Educational level and/ or socio-economic situation that makes it unlikely for the family to fulfil this study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2009
Enrollment:	100

Type:	Actual

Ethics review

Approved WMO Date:	08-12-2008
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

No registrations found.

In other registers

Register	ID
CCMO	NL24290.091.08

Study results

Date completed:	01-01-2014
Actual enrolment:	51