Train your brain with neurofeedback and exercise: advancing the treatment for ADHD

Published: 18-05-2010
Last updated: 04-05-2024

The objective of the proposed research is to address the effectiveness of neurofeedback and exercise as non-pharmacological treatments for ADHD. The effects of neurofeedback and exercise will be assessed on three domains: behaviour, neurocognition,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON36468

Source
ToetsingOnline

Brief title
Train your brain

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
ADHD, hyperkinetic syndrom

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMW (NWO)

Intervention

Keyword: ADHD, EEG, exercise, neurofeedback

Outcome measures

Primary outcome

ADHD symptoms

Secondary outcome

Neurocognition and Neurophysiology (QEEG and ERPs)

Study description

Background summary

ADHD is usually treated with methylphenidate, a widely established treatment. Neurofeedback is becoming an increasingly popular non-pharmacological treatment for ADHD but randomized controlled trials at the efficacy are lacking and the origins of the observed improvements are poorly understood. Another non-pharmacological intervention that has positive effects on neurocognition in various populations is physical exercise. However, virtually nothing is known about the effects of exercise in ADHD. Goal of the proposed research is to examine the effects of neurofeedback and exercise on behaviour, neurocognition and neurophysiology in children with ADHD and subsequently compare these effects with each other and with methylphenidate.

Study objective

The objective of the proposed research is to address the effectiveness of neurofeedback and exercise as non-pharmacological treatments for ADHD. The effects of neurofeedback and exercise will be assessed on three domains: behaviour, neurocognition, and neurophysiology.

Study design

This study is a pragmatic RCT with three treatment arms (MPH, neurofeedback and exercise) and three outcome domains (behaviour, neurocognition and neurophysiology).

Intervention

Neurofeedback

Children will be trained with the neurofeedback system Theraprax using standardized protocols. The training will be presented like a computer game. At the beginning of each session, baseline values are determined during a resting condition followed by ten feedback trials of 2 minutes in length with a one-minute break between the trials. On these feedback trials, the theta/beta ratio is represented by a cartoon on a computer screen. This cartoon is moving upwards when the theta/beta ratio is increasing and down when the theta/beta ratio is decreasing, thus the child is provided with continuous feedback. The goal is to decrease activity in the theta band and to increase activity in the beta band (decrease the theta/beta ratio) at the vertex (electrode Cz) in order to reach a predetermined threshold. This may be achieved by an attentive but relaxed state. If a child reaches this threshold, positive feedback is given. The threshold is based on baseline values in order that positive feedback will be received about 70% of the trials. If children improve their performance, the threshold will be set at a more difficult level in the next session. In addition of these feedback-trials, children will also perform transfer trials, were no continuous feedback is provided on the screen during the trial, but only after the trial. The proportion of transfer trials will gradually increase during the training phase. The aim of these transfer trials is to prepare for generalization of learned activation into daily-life situations. The neurofeedback training will consist of 30 sessions of 45 minutes (including the attachment of electrodes), three times a week. All sessions will be supervised by master students clinical neuropsychology, clinical psychologists and a junior researcher, who will receive extensive training for the purpose of this study. The sessions will be videotaped for treatment integrity checks and to assure treatment quality.

Exercise

Exercise will include various forms of aerobic training in a fitness centre at about 70-100% of their maximum heart rate. This is a level of exercise that has been shown to evoke dopaminergic responses in rat (Hattori et al., 1994) and to have effects on the catecholamine response in children with ADHD (Wigal et al., 2003; Tantillo et al., 2001). The session will consist of series of ten 2 minutes bouts of exercise with 1 minute rest intervals between two exercise bouts. This approach will be used because it is difficult for children to sustain constant exercise for more than several minutes at a time. In fact, typical bouts of exercise in children last only 25-30 seconds (Bailey et al., 1995). The intensity of the exercise sessions will be controlled by using heart rate monitors. The exercise regime will be comparable with the neurofeedback training in intensity and will consist of 30 sessions of 45 minutes (including putting on other clothes and taking a shower), three times a week, following the well-established guidelines of an exercise regime for older adults. The exercise sessions will also be supervised by master students clinical

neuropsychology and human movement sciences, who will receive extensive training for the purpose of this study. The sessions will be videotaped for treatment integrity checks and to assure treatment quality.

Methylphenidate

The children in the MPH (methylphenidate) group will be treated according to the protocol of the ADHD outpatient unit. No additional interventions will be provided to the children. The optimal dose will be determined through a double blind randomised placebo controlled trial. The effects of the medication on behaviour are being monitored by parents and teachers on questionnaires (attention and hyperactivity scales). After five or four weeks (depending on the child's weight), the optimal dose will be selected using standardised algorithms (see Scheres et al., 2003). The children will receive this dose for 3 or 4 weeks followed by post assessment. See protocol for further details.

Study burden and risks

Children and parents will have to put a lot of time and effort in the study (assessement: 3 times 4 hour, treatments, 30 sessions of 45 mintues). The benefits are that the treatments may have a positive effect on ADHD symptoms.

Contacts

Public
Vrije Universiteit

Van der Boechorststraat 1
1081 BT Amsterdam
NL
Scientific
Vrije Universiteit

Van der Boechorststraat 1
1081 BT Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Clinical diagnosis of ADHD.

Exclusion criteria

physical or cognitive disability

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-07-2010
Enrollment:	186
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Methylphenidate
Generic name:	methylphenidatehydrochloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	18-05-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-05-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-10-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2010-020508-31-NL
CCMO	NL31641.029.10