Distractibility in ADHD associated with reduced ability to modulate alpha band oscillations in attentional tasks

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Posner spatial cueing task will be used to investigate electrophysiological differences in brain oscillatory lateralization during attentional shifts in children with and without ADHD. We hypothesize that the observed difference in the ability to...

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

Summary

ID

NL-OMON43451

Source
ToetsingOnline

Brief title
SHARK 2.0

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD, attention deficit and hyperactivity disorder

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Marie Sk□odowska-Curie

Intervention

Keyword: ADHD, Brain Oscillations, Methylphenidate, Structural Connectivity

Outcome measures

Primary outcome

Alpha Modulation Index (AMI) and Alpha Lateralization Index (ALI) will be computed and compared between ADHD and control groups and within ADHD between on- and off-medication conditions; Furthermore the volume of the Superior Longitudinal fascicles will be estimated by means of DTI analysis and the volume of the striatum by means of voxel based morphometry analysis of MRI data.

Primary analysis will then focus on:

- Difference in ALI and AMI between patients and controls and within patients, between conditions MPH and placebo.

- Difference in SLF volume between patients and control.

- Correlation between ALI and SLF lateralization.

- Difference in striatal brain volume between patients and controls.

- Correlation between striatal volume and Alpha Modulation Index.

Secondary outcome

na

Study description

Background summary

Evidence has been recently provided for a major role of alpha activity (8-14Hz) brain response in the active suppression of irrelevant information during attention performance. According to the *inhibition timing hypothesis*, alpha band oscillations show a typical pattern of activity that is reflected by a

decrease in related frequency power in task relevant brain regions contralateral to the attended side, together with a power decrease in task irrelevant regions ipsilateral to the stimulus.
Children with ADHD have recently been reported to show a reduced ability to modulate alpha oscillations during covert attention as compared to typically developing children. This finding is consistent with the notion that alpha band activity has a major role in top-down inhibitory processes which are crucial for attentional selection, whose impairment is indeed a core feature of ADHD symptomatology.
Analyses of structural connectivity in anatomical pathways associated with top down control, in particular the Superior Longitudinal Fasciculus (SLF), have shown a relationship between white matter tract volume and ability to modulate alpha band synchronization during attention performance.
Since, to date, pharmacological intervention represents the most effective treatment of ADHD, a better understanding of the effects of ADHD medication on alpha band modulation during attention performance will likely provide important insights to elucidate the neural bases underlying the symptoms of ADHD.

Study objective

Posner spatial cueing task will be used to investigate electrophysiological differences in brain oscillatory lateralization during attentional shifts in children with and without ADHD. We hypothesize that the observed difference in the ability to modulate alpha activity between ADHD and controls is normalized by stimulant medication (MPH). To this aim two separate conditions will be considered for the ADHD group: Alpha oscillatory activity will be measured on-medication (medication suspended 24 hours prior to the experiment and standardized dosage of MPH administered) and off-medication (medication suspended 24 hours before the beginning of the experiment and placebo administered instead) within a double blind placebo control crossover design.
Moreover, we postulate that patterns of reduced white-matter connectivity and brain volume, along structures typically associated with attention, correlate with the reduced to modulate the specified brain oscillations in ADHD with respect to TD children.
To investigate this hypothesis, in line with Marshall et al. (2015), MEG recording of neural synchronization will be coupled with structural measures reflecting white-matter tract connectivity and brain volume estimation respectively with Diffusion Tensor Imaging (DTI) and Voxel Based Morphometry (VBM) in both groups.

Study design

Alpha activity will be measured by means of MEG recording while children performing a covert attention task.
For the ADHD group, measurements of oscillatory brain activity will be done in

two separate sessions: in both conditions participants will undergo a medication washout of 24 hours (withdrawal of medication) prior to the experiment and subsequently administration of a standardized dosage of ADHD medication or placebo will follow.
Alpha lateralization will be computed and compared between ADHD and controls and between on and off medication in the former group.
MEG data will be coupled with structural measures of white-matter tract connectivity (DTI) and striatal volume estimation (VBM).

Study burden and risks

Participation is not associated with any indications of risks. Burden is minimized as much as possible. Participation is of great importance. Without measurement in this specific target group, generalization of recently obtained new insights in the nature of abnormalities related to ADHD, will not be possible. Because the brain develops during childhood, the only way to be able to draw reliable conclusions in this target group is by comparing results to typically developing children of the same age. In addition, studying this typically developing group will help us understand normal development. Therefore, participation of both groups will be greatly valued. Once we are able to draw reliable conclusions on the nature of differences between typical development and development with ADHD, we will be able to implement these findings in treatment. Clearly, understanding the mechanism underlying ADHD will benefit treatment.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

For both groups inclusion criteria will be: (1) Age between 8 and 12 years. (2) Enrolled in primary (not secondary) school. (3) Estimated IQ above 80.
For the ADHD-group an additional inclusion criterion will be: (1) a clinical diagnosis of ADHD according to the criteria of the DSM-V (see *Study procedures* for detailed description). (2) Scored in the clinical range on the ADHD DSM-IV rating scale, completed by parents. (3) Pharmacological treatment with Methylphenidate (either long- or short-acting formulations), which started at least 3 months before the inclusion in the study.

Exclusion criteria

For both groups exclusion criteria will be: (1) (Co-morbid) psychiatric disorder (major depression, bipolar disorder, psychotic disorder, chronically motor tic disorder or Gilles de la Tourette, Conduct disorder, autism spectrum disorder, eating disorder, anxiety disorder). (2) Neurological disorders (e.g. epilepsy) currently or in the past. (3) Cardiovascular disease currently or in the past. (4) Serious motor or perceptual handicap. (5) Standard MRI Exclusion criteria according to DCCN regulations (see attached pdf in cmo application section: K6: *MR algemene informatie*).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-12-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-04-2017
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

ID: 27284
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56007.091.15
OMON	NL-OMON27284