Towards individual medicine in ADHD: A pilot study on using individual differences in neural reward sensitivity to predict the efficacy of a behavioral intervention in ADHD (The SCORE! study).

Published: 30-04-2014
Last updated: 24-04-2024

To conduct a pilot study on the relationship between measured sensitivity to reward and the effectiveness of a routine cognitive-behavioral intervention in ADHD. To pilot relevant measurements and generate hypotheses for a larger study in the future...

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

Summary

ID

NL-OMON45061

Source
ToetsingOnline

Brief title
The SCORE! study.

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD, Attention Deficit Hyperactivity Disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Hersenstichting Nederland (Kleine Subsidie 2013(1)-217;aan dr. P. de Zeeuw)

Intervention

Keyword: Attention Deficit Hyperactivity Disorder, Behavioral Treatment, Reward Sensitivity

Outcome measures

Primary outcome

1. Change in the severity of ADHD symptoms as a result of treatment, measured with the well-validated Strengths and Weaknesses of ADHD and Normal behavior (SWAN) questionnaire (Lakes, Swanson, & Riggs, 2012).

2. Physiological response to reward as measured by changes in heart rate variability or skin conductance change during both reward tasks.

Secondary outcome

1. Reward sensitivity as measured by (a) the total reward sensitivity score on the SPSRQ-C, the Sensitivity to Punishment and Sensitivity to Reward Questionnaire for children; (b) Reward sensitivity index (response time distribution shift under rewarded versus non-rewarded conditions) from the child-friendly version of the Monetary Incentive Delay task and percentage of advantageous doors chosen from the Hungry Donkey Task (a child-friendly version of the Iowa Gambling Task).

2. Parental ratings of current stress related to parenting their child, as measured by the Nijmeegse Ouder Stress Index (NOSI), which is a translation of

the well-validated Parenting Stress Index.

Study description

Background summary

Attention-Deficit/Hyperactivity Disorder (ADHD) has been extensively related to a reduced sensitivity to reward and reinforcement, which is attributed to dysfunction of the (ventral frontostriatal) reward circuitry of the brain. However, many research groups now suggest that neurobiological heterogeneity is present in ADHD, where some individuals are likely to be more affected by dysfunction of this reward system than others. Standard group cognitive-behavioral interventions in ADHD are based on reinforcement schedules in child-centered sessions and on parent training in reward and reinforcement schedules. However, research shows that such treatments are only modestly effective. One factor explaining this situation might be that this type of intervention will be more efficacious in patients with ADHD where lower sensitivity to reinforcement is not the pivotal area of dysfunction. As such, our hypothesis is that measured sensitivity to reward will predict symptom reduction due to a routine cognitive-behavioral intervention.

Study objective

To conduct a pilot study on the relationship between measured sensitivity to reward and the effectiveness of a routine cognitive-behavioral intervention in ADHD. To pilot relevant measurements and generate hypotheses for a larger study in the future.

Study design

Observational study in the context of a routine cognitive-behavioral intervention for children who have recently been diagnosed with ADHD, and their parents.

Study burden and risks

Children will be asked to perform neuropsychological tasks lasting up to 2 hours. During one hour of this testing, skin conductance (using two finger electrodes), and an electrocardiogram (ECG, using two electrodes placed on the thorax) will be made. No immediate benefits for subjects are to be expected from participation in this study per se, however, subjects are expected to benefit from the routine behavioral treatment this study is an add-on to.

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

Inclusion criteria for patients (children with ADHD):
1. Age between 8;6 (8 years and 6 months) and 12;11 (12 years and 11 months).
2. A clinical diagnosis of ADHD (comorbidities are allowed in order to more closely reflect the typical clinical population), that is confirmed using the Disruptive Behavior Disorders Module (Module E) of the Diagnostic Interview Schedule for Children (DISC) (Schaffer, Fisher, Lucas, Dulcan, & Schwab-Stone, 2000).

Exclusion criteria

1. Estimated IQ < 80, since cognitive behavioral treatments are generally not indicated in

this IQ range.
2. A known (congenital) cardiovascular disease, since this may influence the ECG and subsequent analyses.
3. History of or present neurological disorder. A neurological disorder is defined as any disorder that requires care from a neurologist.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	30-04-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	05-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL47011.041.13