A study on a variant of the Continuous Performance Test: RANDI

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Developmental disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON34603

Source
ToetsingOnline

Brief title
RANDI

Condition

- Developmental disorders NEC

Synonym
Attention hyperactivity deficit disorder (ADHD)

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Yulius (voorheen RMPI De Grote Rivieren)
Source(s) of monetary or material Support: Stichting Yulius (voorheen RMPI-De Grote Rivieren)

Intervention

Keyword: attention, Attention Deficit Hyperactivity Disorder (ADHD), Continuous

performance test (CPT), response inhibition

Outcome measures

Primary outcome

It is expected that older children perform better, will make fewer errors of comission or omission than younger children, and have faster reaction time. It is also expected that during the task, performance will decrease.

Secondary outcome

Girls are expected to have slower reaction time, but have better performance than boys.

Study description

Background summary

Attention deficit hyperactivity disorder (ADHD) is a child psychiatric disorder with a prevalence rate of 5%. ADHD is diagnosed on the basis of systematically collected data from teachers, parents and professionals. However, setting this diagnosis and evaluating the treatment effect could be supported by different neuropsychological tests that can record the core symptoms of ADHD by a more objective measure. The continuous performance task (CPT) is a neuropsychological instrument, which is able to measure the attention span and response inhibition of a child. A lot of different versions of the CPT are developed and used for different age groups. This makes it hard to compare the results on the level of groups and individuals. A new version of the CPT is developed, by RMPI De Grote Rivieren in cooperation with a software developer, and named RANDI. An important advantage of this new version compared to the existing versions is that all relevant parameters can be adjusted separately by the researcher, so the test can be adjusted to the age of the child or adolescent. An important goal for the future is - apart from validating RANDI as a diagnostic instrument - developing a neurocognitive training to practise impulse control and selective attention by using the CPT. In order to use this CPT version as a diagnostic instrument and to develop a trainingprogram, performance data has to be collected for different age groups in a normative population (6-11 year old children).

Study objective

The main aim of this study is to collect normative data on the RANDI for several age groups.

Study design

This is a randomized, single blind study with a cross-over design. 180 participants will be divided into three age groups (6-7 years old, 8-9 years old, and 10-11 years old). The RANDI is a computer task in which geometrical figures (square, circle, triangle) are presented on a computer screen. Figures vary in color (yellow or blue). The participant has the instruction to click the mouse only when the yellow circle is shown. Two conditions are tested: a high target rate condition (HTR: 60% targets) and a low target rate condition (LTR: 20% targets). All children conduct both target rate conditions. Children are randomly assigned to two situations: 1) first the HTR, second the LTR or 2) first the LTR task, second the HTR task. The second task is conducted a week after the first task.

Study burden and risks

The burden of the study is limited. The RANDI will be performed twice by the children; this will take about 40 minutes divided over two days. Because of the short length it is unlikely that participation in the study will disturbe the school routine. Parents of the children will be asked to fill out three questionnaires which will take about 15 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Age between 6 - 11 years old
- Presence of a signed and returned informent consent by the parents and the child

Exclusion criteria

- no exclusion criteria are used

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2011
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	22-10-2010
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (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	NL32889.097.10