

A randomized, controlled study into the effects of food on the behaviour of young children with attention-deficit hyperactivity disorder (ADHD).

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26249

Source

NTR

Brief title

N/A

Intervention

Outcome measures

Primary outcome

Parent and teacher ratings on the 10-item Conners list and the ADHD rating scale. There are three measurement points: (i) the start of the trial; (ii) the end of the baseline period, and (iii) the end of the diet or control period.

Secondary outcome

Parent ratings on oppositional defiant behaviour, aggressive behaviour, compulsive behaviour, nervous tremors or obsessive behaviour.

Parents ratings on other complaints the child may experience. Questions are asked about physical complaints, such as gastrointestinal problems, headaches, stomach aches, eczema,

asthma, ear, nose or throat complaints, nosebleeds, excessive sweating, and sleeping problems.

Study description

Background summary

80 children, 3-8 years old, are randomly assigned to either a diet group or a control group. After a two weeks-baseline period, 40 children will follow a four-week food elimination diet, whilst the children assigned to the control group will be placed on a waiting list; they will adhere to their normal food pattern. Children in the control group are not offered any other treatment. Identical questionnaires and measurement times are used for the two groups and will be completed by parents and teachers at the start of the trial, after the baseline period and after the diet- or controlperiod. Following the final measurement, families in the control group may also choose to start the food elimination diet.

Study objective

The effects of foods on children with ADHD will be determined in a randomized, controlled trial. Can the results of earlier open-diet trials in the Netherland, i.e. 60% of the participants showed an improvement in behaviour of 50% or more, be confirmed? The prediction tested is that a few foods diet wil lead to a significant improvement of behaviour in children with ADHD.

Intervention

The children are assigned at random to either a diet group or a control group. Each group consists of 40 children. Following the baseline period, the children placed in the diet group will follow a 4-week food elimination diet, whilst the children assigned to the control group will be placed on a waiting list; they will adhere to their normal food pattern. Children in the control group are not offered any other treatment. Identical questionnaires and measurement times are used for the two groups. Following the final measurement, families in the control group may also choose to start the food elimination diet.

Contacts

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Eligibility criteria

Inclusion criteria

1. ADHD combined subtypes or hyperactive/impulsive subtypes diagnosed according to DSM IV; diagnoses based on structured psychiatric interviews and standard questionnaires (10-item Conners list and ADHD rating scale) to be completed by parents and teachers;
2. Children aged between three and eight;
3. Children not taking or not responding adequately to medication;
4. Behavioural problems originating prior to children reaching the age of four.

Exclusion criteria

1. Adopted children and foster children;
2. Children taking and responding to medication;
3. Co-existing neurological diseases, such as epilepsy, neurofibromatosis, etc.;
4. IQ below 70;
5. Alcohol/drugs use or smoking by mother during pregnancy;
6. Prematurity/dysmaturity (children born before 36th week of pregnancy or with a weight below 1500 grams) or problems during delivery requiring admission to the neonatal intensive care unit;
7. Children diagnosed PDD, PDD-NOS and/or MCDD.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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
NTR-new	NL205
NTR-old	NTR242
Other	: N/A
ISRCTN	ISRCTN47247160

Study results

Summary results

N/A