

# A randomised, controlled study into the effects of food on the behaviour of young children with attention-deficit hyperactivity disorder

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/01/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr J Karman

**Contact details**  
Landluststraat 15  
Middelburg  
Netherlands  
4337 KA  
-  
janckarman@planet.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

A randomised, controlled study into the effects of food on the behaviour of young children with attention-deficit hyperactivity disorder

## Study objectives

The effects of foods on children with Attention-Deficit Hyperactivity Disorder (ADHD) will be determined in a randomised, controlled trial. Can the results of earlier open-diet trials in The Netherlands (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 will lead to a significant improvement of behaviour in children with ADHD.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Prospective randomised, active controlled, parallel group treatment, efficacy, monocentric trial.

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Attention Deficit Hyperactivity Disorder (ADHD)

## Interventions

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 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. Following the final measurement, families in the control group may also choose to start the food elimination diet.

Scientific contact: Ms. L.M.J. Pelsser, lmjpelsser@worldmail.nl

Please note that the anticipated start and end dates of this trial have changed to 1st May 2007 and 1st May 2010 respectively.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Parent and teacher ratings on the 10-item Conners list and the ADHD rating scale. There are three measurement points:

1. The start of the trial
2. The end of the baseline period, and
3. The end of the diet or control period

## **Secondary outcome measures**

1. Parent ratings on oppositional defiant behaviour, aggressive behaviour, compulsive behaviour, nervous tremors or obsessive behaviour
2. 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

## **Overall study start date**

01/08/2005

## **Completion date**

01/12/2006

# **Eligibility**

## **Key inclusion criteria**

1. ADHD combined subtypes or hyperactive/impulsive subtypes diagnosed according to Diagnostic and Statistical Manual of mental disorders fourth edition (DSM IV); diagnoses based on structured psychiatric interviews and standard questionnaires (ten-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

## **Participant type(s)**

Patient

## **Age group**

Child

## **Lower age limit**

3 Years

**Upper age limit**

8 Years

**Sex**

Not Specified

**Target number of participants**

80

**Total final enrolment**

27

**Key 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. Intelligence Quotient (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 Pervasive Developmental Disorder (PDD), Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS) and/or Multiple-Complex Developmental Disorder (MCDD)

**Date of first enrolment**

01/08/2005

**Date of final enrolment**

01/12/2006

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

Landluststraat 15

Middelburg

Netherlands

4337 KA

**Sponsor information****Organisation**

Child Psychiatry Department of Radboud University Nijmegen (The Netherlands)

**Sponsor details**

c/o Prof. J.K. Buitelaar  
Child and adolescent psychiatrist  
Reinier Postlaan 10  
Nijmegen  
Netherlands  
6500 HB

**Sponsor type**

University/education

**ROR**

<https://ror.org/05wg1m734>

**Funder(s)****Funder type**

Charity

**Funder Name**

Foundation for Children's Welfare Stamps Netherlands (The Netherlands)

**Funder Name**

Foundation Nuts Ohra (The Netherlands)

**Funder Name**

Matty Brand Foundation (The Netherlands)

**Funder Name**

Foundation of Child and Behaviour (Stichting Kind en Gedrag) (The Netherlands)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2010	07/01/2021	Yes	No