

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 years

Upper age limit

8 years

Sex

Not Specified

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)

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

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/09/2010 | 07/01/2021 | Yes | No |