ISRCTN76063113 https://doi.org/10.1186/ISRCTN76063113

The INCA study: a study into the Impact of Nutrition on Children with Attention-Deficit Hyperactivity Disorder (ADHD)

Submission date
10/12/2007

Recruitment status
No longer recruiting

Registration date
07/01/2008

Overall study status
Completed

Last Edited
09/02/2011

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SKN-18511/3/19; SNO-T-0602-48

Study information

Scientific Title
A Dutch randomised controlled trial into the effects of food on the behaviour of a random group of school-going children meeting the Diagnostic and Statistical Manual of Mental

Disorders, 4th edition (DSM-IV) criteria for Attention-Deficit Hyperactivity Disorder (ADHD), including immunological testing

Acronym
INCA

Study objectives
Attention-Deficit Hyperactivity Disorder (ADHD) is a psychiatric disorder which affects 3 to 5% of all school-going children. The disorder generally manifests itself before the age of 7 and is characterised by symptoms of inattention, impulsive behaviour and hyperactivity. ADHD is generally diagnosed in combination with other psychiatric disorders such as Oppositional Defiant Disorder (ODD) and Conduct Disorder (CD).

The trial is two-phased, an elimination phase and a reintroduction phase.

The objective of the elimination phase is to determine the impact of an elimination diet on the behaviour of a heterogeneous, random group of children with ADHD. The null hypothesis is that there is no effect of treatment (i.e. food elimination) on the behavioural scores of the subjects.

The objective of the reintroduction phase is to examine whether Immunoglobulin G (IgG) and Immunoglobulin E (IgE) blood testing is useful in children with ADHD and whether the determination of antibodies to specific foods may simplify the diagnostic procedure in children responding to an elimination diet. The null hypothesis is that there is no effect of treatment, i.e. there is no relationship between the level of IgE or IgG antibodies in the blood and the behavioural scores of the subjects.

Please note that this is a follow-up study to the previously registered trial entitled 'A randomised, controlled study into the effects of food on the behaviour of young children with attention-deficit hyperactivity disorder' [ISRCTN47247160] - see http://www.controlled-trials.com/ISRCTN47247160.

Please note that as of 23/09/08 this trial record was updated. The initial anticipated start and end dates of this trial was as follows:
Initial anticipated start date: 01/02/2008
initial anticipated end date: 01/02/2011
All other changes to this record can be found in the relevant field.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Medical Ethics Committee of the Wageningen University on the 13th November 2007 (ref: ABR NL 12736.081.06).

Study design
The INCA study is a randomised, controlled, single-blind, multicentre, interventional study.

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Attention-deficit hyperactivity disorder (ADHD)

Interventions
Current interventions as of 23/09/2008:
All children will be randomly assigned to either a diet group or a control group. Each group consists of 50 children. From each child at least two blood samples will be taken, at the start and at the end of the trial.

Following a baseline period (week 1 - 3), the control group will be placed on a waiting list and will receive no treatment (week 3 - 9). They will receive broad recommendations for a healthy diet. Both groups have to keep an extended diary. The diet group will receive the active treatment, a five weeks elimination diet (week 3 - 9). All major allergen foods, ingredients and/or additives associated with behavioural disorders are eliminated from the diet. The diet basically consists of bread, rice, corn, turkey, lamb, various vegetables and fruits, rice milk with extra calcium, margarine, and pear juice from concentrate. This basis is complemented with specific foods like potatoes, fruits, corn, some sweets and wheat, allowed in limited doses twice a week. Vegetables, fruits, rice and meat are allowed every day. Occasionally the diet will be varied to avoid foods for which the child has a particular craving or dislike. The diet clearly prescribes for each day which products and snacks the child may eat and drink. The diet is adjusted to the individual child in order to take into account the childs specific food preferences and to leave out all foods which the child does not like. If the diet does not result in any behavioural changes after the first two weeks, the diet will be further restricted in consultation with the parents. In the end, therefore, the diet may vary for each individual child, depending on the need to make interim adjustments.

The reintroduction phase (week 9 - 13), is based on the IgE and IgG levels, determined in the first blood test. The control group is still on the waiting list (week 9 - 13), the responders of the diet group will proceed with the reintroduction phase during which all foods with IgG-0 value and without increased IgE level will be reintroduced concurrently to the diet of the responders, in a double-blind cross over design.

Following the final measurements at week 13, all children from the control group will be offered an opportunity to start the elimination diet.

Initial interventions:
All children will be randomly assigned to either a diet group or a control group. Each group consists of 50 children. From each child at least two blood samples will be taken, at the start and at the end of the trial.

Following a baseline period (week 1 - 3), the control group will be placed on a waiting list and will receive no treatment (week 3 - 9). They will receive broad recommendations for a healthy diet. Both groups have to keep an extended diary. The diet group will receive the active treatment, a five weeks elimination diet (week 3 - 9). All major allergen foods, ingredients and/or additives associated with behavioural disorders are eliminated from the diet. The diet basically consists of bread, rice, corn, turkey, lamb, various vegetables and fruits, rice milk with extra calcium, margarine, and pear juice from concentrate. This basis is complemented with specific foods like potatoes, fruits, corn, some sweets and wheat, allowed in limited doses twice a week. Vegetables, fruits, rice and meat are allowed every day. Occasionally the diet will be varied to avoid foods for which the child has a particular craving or dislike. The diet clearly prescribes for

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Following the final measurements at week 13, all children from the control group will be offered an opportunity to start the elimination diet.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The Abbreviated Conners Scale (ACS) and the ADHD Rating Scale (ARS) are the two major rating scales for the outcomes of this study. They will be used during all measurement points, i.e. M1 (week 0), M2 (week 3), M3 (week 9), M4 (week 11) and M5 (week 13).

1. The ACS consists of 10 questions using a 4-point scale. A score of 15 represents two standard deviations above the mean cut-off. Scores can range from 0 to 30. The ACS will be completed by both the parents and the teacher
2. The ARS is based on the DSM-IV and consists of 9 inattention items and 9 hyperactivity /impulsivity items, and uses a 4-point scale. The answers to each question vary from Never or Rarely (0 points), Sometimes (1 point), Often (2 points) to Very Often (3 points). The ARS will be completed by the parents, teachers and the blinded paediatrician

Key secondary outcome(s))
1. A Structured Psychiatric Interview (SPI), based on DSM-IV criteria, will be used to assess comorbid disorders, like ODD and CD. This interview is taken at M1 (week 0), M3 (week 9) and M5 (week 13) and will be completed by the parents, the teacher and the blinded paediatrician
2. The Strengths and Difficulties Questionnaire (SDQ) is a brief behavioural screening questionnaire, concerning emotional and conduct problems, hyperactivity/inattention, peer relationship and prosocial behaviour. The answers to each question are Not True, Somewhat True or Certainly True. Parents and the childs teacher will fill in the SDQ at M2 (week 3), M3 (week 9) and M5 (week 13)
3. Physical complaints of the child will be identified with the Other Complaints Questionnaire. The questions concern the presence or absence of physical complaints such as gastrointestinal problems, headaches, eczema, unusual perspiration, sleep disturbances and asthma. The answers to each question are Yes (often complaints) or No (seldom or never complaints). Parents must fill in the questionnaire at M2 (week 3), M3 (week 9) and M5 (week 13)
4. All IgG-scores, IgE-scores and other blood values will be analysed

Completion date

01/09/2011

Eligibility

Key inclusion criteria
1. ADHD diagnosed according to Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV); diagnoses based on structured psychiatric interviews and standard questionnaires (Abbreviated Conners Scale, ADHD Rating Scale, Strengths and Difficulties Questionnaire) to be completed by parents and teachers
2. Children aged between 4 and 8
3. Children not taking medication such as methylphenidate
4. Parental permission for three blood tests
5. Sufficient command of the Dutch language

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
1. Family circumstances hampering completion of the elimination diet
2. Children already on a diet or having been on a diet in the past two months
3. Children receiving behavioural therapy or medication at the time of registration

Date of first enrolment
01/09/2008

Date of final enrolment
01/09/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
ADHD Research Centre
Eindhoven
Netherlands
5624 JE

Sponsor information

Organisation
Wageningen University (The Netherlands)

ROR
https://ror.org/04qw24q55

Funder(s)

Funder type
Research organisation

Funder Name
The Nuts-Ohra Foundation (Stichting Nuts Ohra [SNO]) (The Netherlands) (ref: SNO-T-0602-48)

Funder Name
The Foundation for Childrens Welfare Stamps Netherlands (Stichting Kinderpostzegels Nederland [SKN]) (ref: SKN-18511/3/19)

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	05/02/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes