Effects of N-3 fatty acids (DHA and EPA) on cognitive control and associated brain activity in ADHD: A double-blind placebo controlled study

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The objective of the present study is to investigate whether a diet rich in n-3 fatty acids (DHA/EPA) can improve brain activation patterns assiociated with cognitive control in children with ADHD .

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Developmental disorders NEC
Study type	Interventional

Summary

ID

NL-OMON35299

Source
ToetsingOnline

Brief title
N-3 fatty acids in ADHD

Condition

- Developmental disorders NEC

Synonym
ADHD, attention deficit

Research involving
Human

Sponsors and support

Primary sponsor: Unilever

Source(s) of monetary or material Support: Unilever,Voedingsmiddelen industrie (zie G2)

Intervention

Keyword: ADHD, cognitive control, fMRI, n-3 fatty acids

Outcome measures

Primary outcome

The primary outcome measure is changes in MR signal with n-3 supplementation.

Secondary outcome

The secondary outcome measures are changes with n-3 supplementation in:

1) cognitive control (Accuracy and RT on the go/no-go task)

2) ADHD symptoms

3) fatty acid status assessed in cheek cells

4) dopamine metabolites assessed in urine

Study description

Background summary

Children with ADHD have been shown to have a lower status of the n-3 fatty acid DHA compared to healthy
children. Moreover, some clinical trials have shown that EPA and DHA supplementation of children with ADHD
may alleviate symptomatology and may improve cognitive performance.

Study objective

The objective of the present study is to investigate whether a diet rich in n-3 fatty acids (DHA/EPA) can
improve brain activation patterns assiociated with cognitive control in children with ADHD .

Study design

Randomized, placebo controled, double-blind, parallel design, where children with and without ADHD receive a
food supplement for 16 weeks (n-3 fatty acids or placebo) and participate in a pre- and post-measurement
using fMRI.

Intervention

The intervention group will receive 10 grams of margarine enriched with n-3 daily for 16 weeks. The placebo
group will receive a similar product, without the n-3 enrichment.

Study burden and risks

The overall burden and risks of the study are minimal. DHA and EPA will be integrated in a regular dietary
product (margarine), which has been tested for microbiological and general safety. All ingredients are food
grade. No specific risks exist for the intervention product. The study will involve five site visits for participants
and their parents. During the visits at the start and at the end of the intervention children will participate in an
fMRI-scan and a protocolized simulation session. The purpose of this session is to prepare children for the
fMRI-scan and to assess whether they are willing to and capable of participating in the actual session. Parents
and teachers of children will be asked to fill out questionnaires pertaining to the child*s behaviour, dietary fat
intake and to assess symptoms of fatty acid deficiency. For each questionnaire this will take between 5 and 20
minutes of their time. At all five visits, participants will be asked to fill out additional questionnaires (on dietary
fat intake and ADHD behaviour) and to donate urine samples. Before the start of the intervention and after
completion, buccal cells will be collected by means of a cheek swab.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

General:
1) 8-14 year old boys
2) Used to daily consumption of margarine
3) Sufficient mastery of the Dutch language of both the subject and his parents
ADHD-group:
1)DSM-IV (APA, 1994) diagnosis of ADHD, according to DISC interview
2) Scores in the clinical range on the Child Behaviour Checklist (CBCL) and Teacher Rating Form(TRF)

Exclusion criteria

1) mental retardation (IQ < 70)
2) major illness of the cardiovascular, the endocrine, the pulmonary or the gastrointestinal system
3) presence of metal objects in or around the body (pacemaker, dental braces)
4) history of or present neurological disorder
5) regular use of n-3 or n-6 fatty acid dietary supplements, products fortified with EPA or DHA, a regular diet high in fatty fish in the four months prior to study participation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2009
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	11-11-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-01-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-11-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (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	NL24118.041.08