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Omega-3 fatty acids supplementation for adolescent boys with attention deficit hyperactivity disorder: a double-blind, randomized controlled trial

Submission date 10/03/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 09/05/2006	**Overall study status** Completed	
Last Edited 20/06/2016	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Omega-3 fatty acids supplementation for adolescent boys with attention deficit hyperactivity disorder: a double-blind, randomized controlled trial

Acronym
MAAFA

Study objectives
Omega-3 fatty acids supplementation for 3 months is effective and safe to improve symptoms of attention deficit hyperactivity disorder in male adolescents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Subjects receiving 6 capsules a day for three months either:
1. 558 mg eicosapentaenoic acid (EPA), 174 mg docosahexaenoic acid (DHA) and 60 mg gamma-linolenic acid (GLA) (per day)
2. 3 g Middle Chain Trygliceride oil with fishy flavour per day (Placebo)

Intervention Type
Supplement

Primary outcome measure
Conners teacher rating scale ADHD index

Secondary outcome measures
1. Fatty acids deficiency questionnaire
2. 4-Day dietary patterns questionnaire
3. Buss-Perry aggression scale
4. Strength and difficulty questionnaire
5. Depression Anxiety Stress Scales
6. Barratt impulsivity scale
7. Electroencephalography/event-related potential
8. Blood test (phospholipid fatty acids status in red blood cell and plasma)
9. Conners parent rating scale
10. Neurophysiological measures

Overall study start date
20/03/2006

Completion date
30/09/2007

Eligibility

Key inclusion criteria
1. Male adolescents aged 12-17 years of age from special schools in London and Kent in the UK
2. Subjects who meet ADHD diagnosis criteria using a structured interview (CHIPS) based on Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria
3. Subjects who have Conners Parents ADHD Rating Global Scale and Conners Teachers ADHD Rating Global Scale above 65

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
17 Years

Sex
Male

Target number of participants
60

Key exclusion criteria
1. Subjects who took omega-3 supplement within 6 months
2. A personal history of diabetes or other metabolic disorder influencing fatty acid metabolism
3. Subjects who are not living in a family home or residential school
4. Subjects who are under special diets (e.g. vegetarian, taking supplements)
5. Subjects who are not in school during the intervention
6. Serious or chronic disease
7. Low blood coagulation function (e.g. haemophilia, hepatic dysfunction, low-vitamin K)
8. Under these medications: alpha tocopherol, selected anticoagulants (aspirin, warfarin, heparin), cyclosporine, clopidogrel, etretinate and topical steroids, cholesterol-lowering medications (atorvastatin, lovastatin, and simvastatin), non-steroidal anti-inflammatory drugs (NSAIDs), dalteparin, dipyrdamole, enoxaparin, ticlopedine
9. Known allergy for fish product derivatives, Vitamin E derivatives, gelatine
10. Abnormal blood data in the baseline assessment
11. All subjects will score higher than 70 on the prorated IQ as measured by The Kaufman Brief Intelligence Test (K-BIT)
12. For the electroencephalogram (EEG) studies only, subjects with left handed, neurological problems or substance abuse will be excluded

Date of first enrolment
20/03/2006

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry
London
United Kingdom
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Sponsor information

Organisation
King's College London (UK)

Sponsor details

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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
The Mother and Child Foundation (registered charity number 1037513) (UK)

Funder Name
Equazen Nutraceutical Ltd. will provide capsules (UK)

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?
Results article	results	01/12/2015		Yes	No