

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	<input type="checkbox"/> Prospectively registered
Registration date 09/05/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/06/2016	Condition category 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

Dr Eric Taylor

Contact details

Child and Adolescent Psychiatry
Institute of Psychiatry
P085 De Crespigny Park
London
United Kingdom
SE5 8AF

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e.taylor@iop.kcl.ac.uk

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 Triglyceride 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, dipyridamole, 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

SE5 8AF

Sponsor information

Organisation

King's College London (UK)

Sponsor details

Institute of Psychiatry
De Crespigny Park
London
England
United Kingdom
SE5 8AF
-
g.dale@iop.kcl.ac.uk

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