

# 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

**Registration date**  
09/05/2006

**Overall study status**  
Completed

Statistical analysis plan

Results

**Last Edited**  
20/06/2016

**Condition category**  
Mental and Behavioural Disorders

Individual participant data

## 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

## 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

**Study type(s)**

Treatment

**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(s)**

Conners teacher rating scale ADHD index

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

12 years

**Upper age limit**

17 years

**Sex**

Male

**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**

United Kingdom

England

**Study participating centre**

**Institute of Psychiatry**

London

United Kingdom

SE5 8AF

## **Sponsor information**

**Organisation**

King's College London (UK)

**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

## 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?
<a href="#">Results article</a>	results	01/12/2015		Yes	No