ISRCTN27741572 https://doi.org/10.1186/ISRCTN27741572

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

Registration date
09/05/2006

Overall study status
Completed

Last Edited
20/06/2016

Condition category
Mental and Behavioural Disorders

[ ] 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
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

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?
Results article	results	01/12/2015		Yes	No