

The Middlesbrough study: a randomised, controlled trial of dietary supplements with omega-3/omega-6 fatty acids in mainstream school children

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/11/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

Study information

Scientific Title

Study objectives

Omega-3 consumption in children in western Countries has been declining. At the same time there has been concerns about the increased levels of poor concentration, hyperactivity and learning difficulties evidenced in the UK school population. Of these children a proportion (30%) do not appear to respond to standard interventions and a large proportion were found to have eczema, asthma, lactose intolerance and other allergies that may be related to dietary deficiencies. The focus of this study is to determine the effect of dietary intervention on learning and behavioural conditions.

Previous Randomised Controlled Trials (RCTs) have indicated a positive effect on reducing hyperactivity and improved educational attainment in children with specific learning difficulties (Dyslexia/Developmental Coordination Disorder [Dyspraxia] and Attention Deficit Hyperactivity Disorder [ADHD]) following dietary supplementation with omega-3/omega-6 fatty acids. This trial will test the hypothesis that similar effects are evident with dietary omega-3/omega-6 supplementation in a cross-section of mainstream schoolchildren, who do not have diagnosed learning difficulties/behavioural problems.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval was sought in March 2005 from South Tees Local Research Ethics Committee. At that time, the committee stated "This study does not fall within Section 3 of Governance Arrangements for Research Ethics Committees (GAFREC), which identifies that ethical advice from the appropriate NHS REC is required for any research involving activities within Section 3.1 a-g".

The committee were asked to review their decision and their response has been:

"In accordance with Section 1.88 of the Standard Operating Procedures for Research Ethics Committees (SOPs), I have been asked to review the file and to comment. I have been asked for my opinion as Chair of County Durham and Tees Valley 1 REC. I was Chair of South Tees LREC in April 2005.

"If submitted for full review by the LREC, it must be judged by the standard and requirements at the time, that is Spring 2005. This project is an extension of previous work, but in this case specifically looking to recruit a different child population, including children that were educationally underachieving.

"The research team and facilities were appropriate. The only identified risk was a minimal risk of mild digestive upset with a reported rate of 3%. Standard psychometric assessments were proposed. Children were randomly allocated to the active or a placebo supplement and the researchers were 'blinded' to the allocation.

"The welfare of all the participants was appropriately safeguarded and the exclusion criteria sensible.

"The provision of information to the school staff, general practitioners, parents and children were satisfactory and consent dealt with appropriately. In my view, the Committee at that time would have given a 'favourable' opinion."

Study design

Interventional, multi-centre, randomised double-blind, placebo controlled, one-way crossover study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Poor concentration, hyperactivity, learning abilities and working memory

Interventions

Active treatment: dietary supplement (Eye q):

Omega-3/omega-6 dietary supplement in capsule form, six times/day providing 558 mg Eicosapentaenoic Acid (EPA), 174 mg Docosahexaenoic Acid (DHA), 60 mg Gamma Linolenic Acid for duration of trial.

Control group: dietary supplement (placebo):

Placebo containing medium-chain triglycerides derived from olive oil, 4% of the capsule comprised EPA and DHA to ensure a fishy taste and carrot oil macerate for colouring. After three months this group crossed over to the active treatment.

The duration of the treatment was six months (one-way crossover from placebo to active after three months) with staggered entry over two months. Assessments for primary/secondary outcome measures were completed at baseline, three and six months. A random sample of 50 participants will be tracked until they leave school, aged 16/18. Follow up will involve monitoring participants' attainments in National Tests (KS 1, 2 and 3 results and performance at KS4 via GCSE/Vocational qualifications).

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Omega-3/omega-6 supplements (including Eicosapentaenoic Acid, Docosahexaenoic Acid, Gamma Linolenic Acid)

Primary outcome measure

1. Measurement of change in working memory, confirmed by results from Wechsler Intelligence Scale for Children (WISC-III UK) digit span assessment; time frame: 6 months
2. Measurement of change in reading ability, using the Wechsler Objective Reading Dimensions (WORD) assessment; time frame: 6 months

Secondary outcome measures

1. Measuring a range of behavioural parameters including cognitive problems, hyperactivity, social problems, ADHD and emotional lability as identified by parents using the Conners' Parent Rating Scales-Long Version (CPRS-L); time frame: 6 months
2. Measuring a range of behavioural parameters including cognitive problems, hyperactivity, social problems, ADHD and emotional lability as identified by teachers using the Conners' Teacher Rating Scales-Long Version (CTRS-L); time frame: 6 months

Overall study start date

01/04/2005

Completion date

31/01/2006

Eligibility

Key inclusion criteria

Participants attend mainstream school.

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

250

Key exclusion criteria

Children with:

1. Significant neurological problems
2. Psychiatric conditions
3. Any of the following medical problems:
 - 3.1. Epilepsy
 - 3.2. Cerebral palsy
 - 3.3. Multiple sclerosis
 - 3.4. Myalgic encephalopathy

- 3.5. Pervasive developmental disorder
- 3.6. Autism
- 4. Diagnosed ADHD
- 5. Consumption of essential fatty-acid supplementation within previous three months

Date of first enrolment

01/04/2005

Date of final enrolment

31/01/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Education Development Centre

Spennymoor

United Kingdom

DL16 6JE

Sponsor information

Organisation

Durham County Council (UK)

Sponsor details

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Sponsor type

Government

Website

<http://www.durham.gov.uk/>

ROR

<https://ror.org/05bt4z39>

Funder(s)

Funder type

Government

Funder Name

Middlesbrough Council (UK) - funding

Funder Name

Durham County Council (UK) - funding

Funder Name

Equazen Ltd (UK) - provided active and placebo treatments

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